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(54) **OCULAR IMPLANT WITH STIFFNESS QUALITIES, METHODS OF IMPLANTATION AND SYSTEM**

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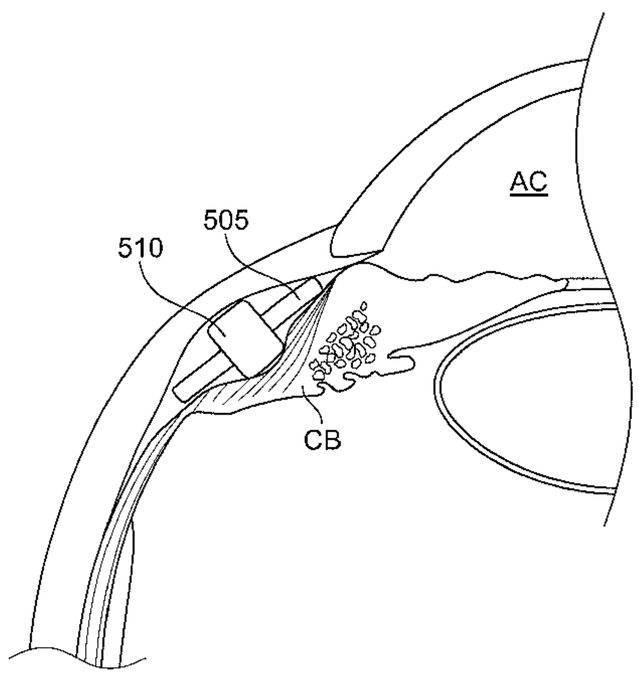
(57) **ABSTRACT**

Described herein are devices and methods for treating eye conditions. Described is an ocular implant including an elongate member having an internal lumen forming a flow pathway, at least one inflow port communicating with the flow pathway, and at least one outflow port communicating with the flow pathway. The elongate member is adapted to be positioned in the eye such that at least one inflow port communicates with the anterior chamber, at least one outflow port communicates with the suprachoroidal space to provide a fluid pathway between the anterior chamber and the suprachoroidal space when the elongate member is implanted in the eye. The elongate member has a wall material imparting a stiffness to the elongate member. The stiffness is selected such that after implantation the elongate member deforms eye tissue surrounding the suprachoroidal space forming a tented volume.

27 Claims, 12 Drawing Sheets



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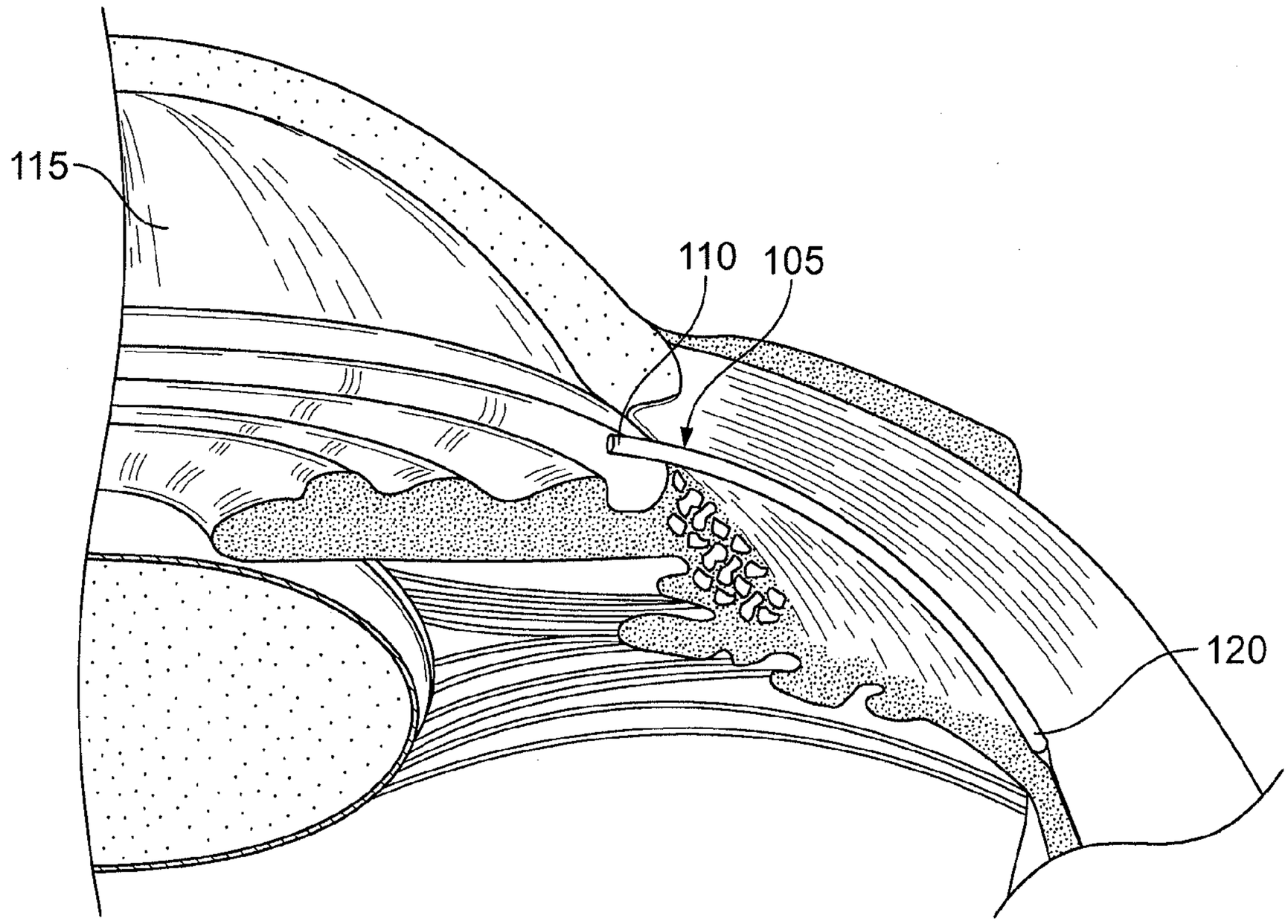


FIG. 1

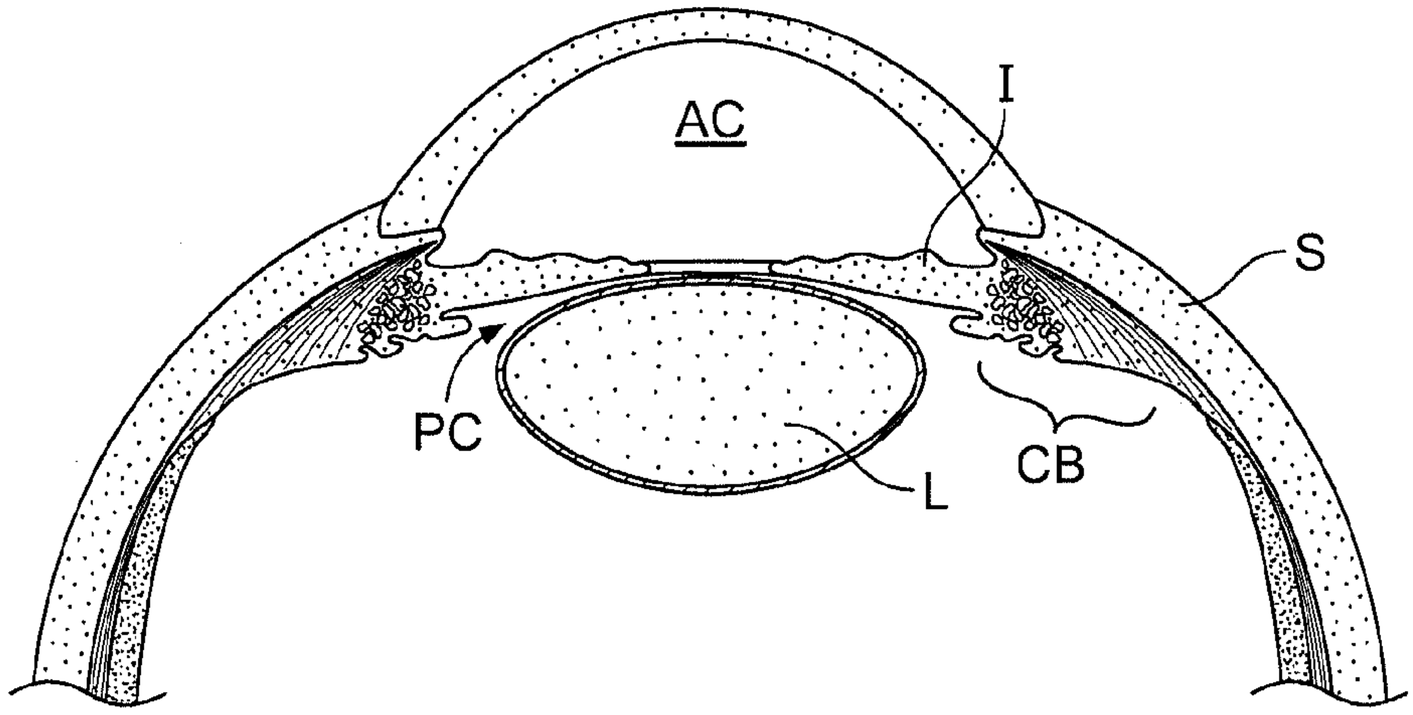
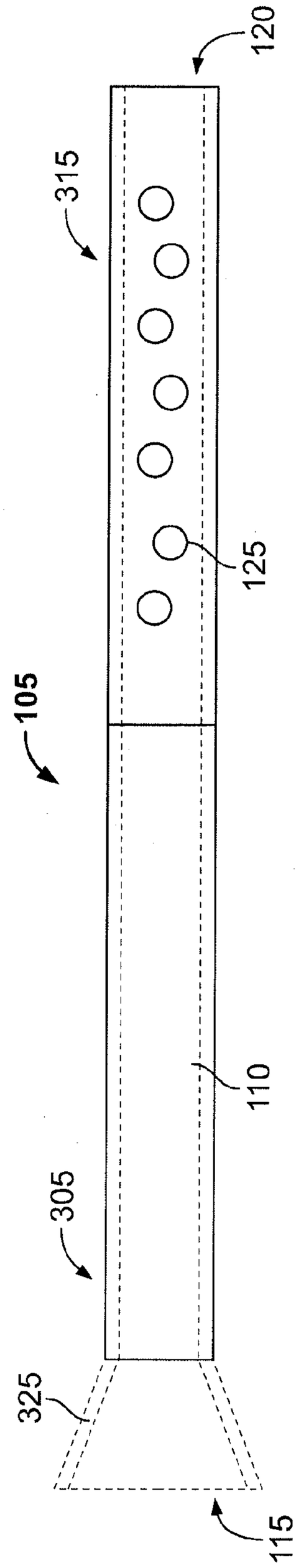


FIG. 2



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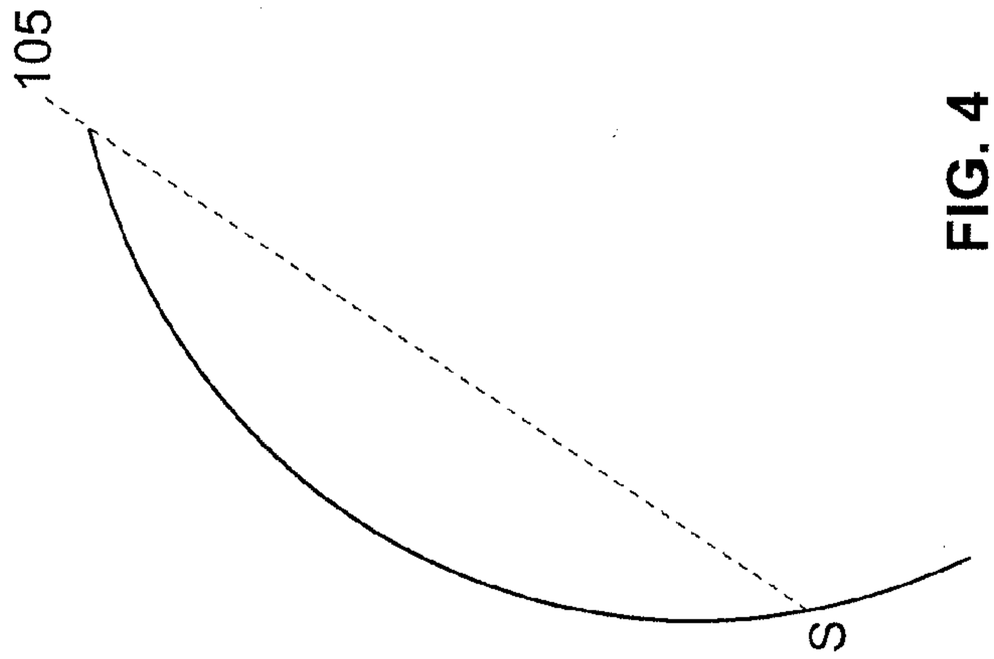

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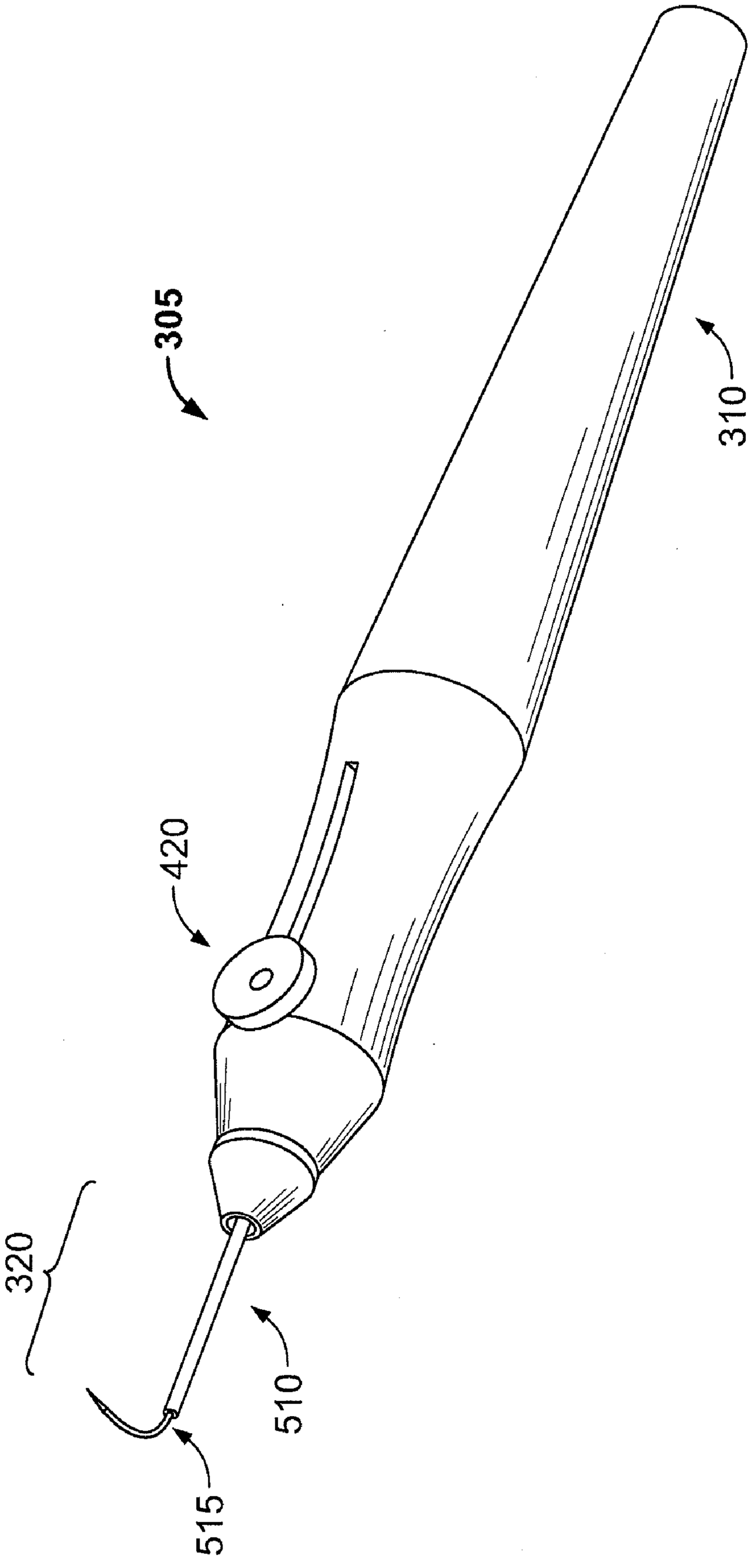

FIG. 5A

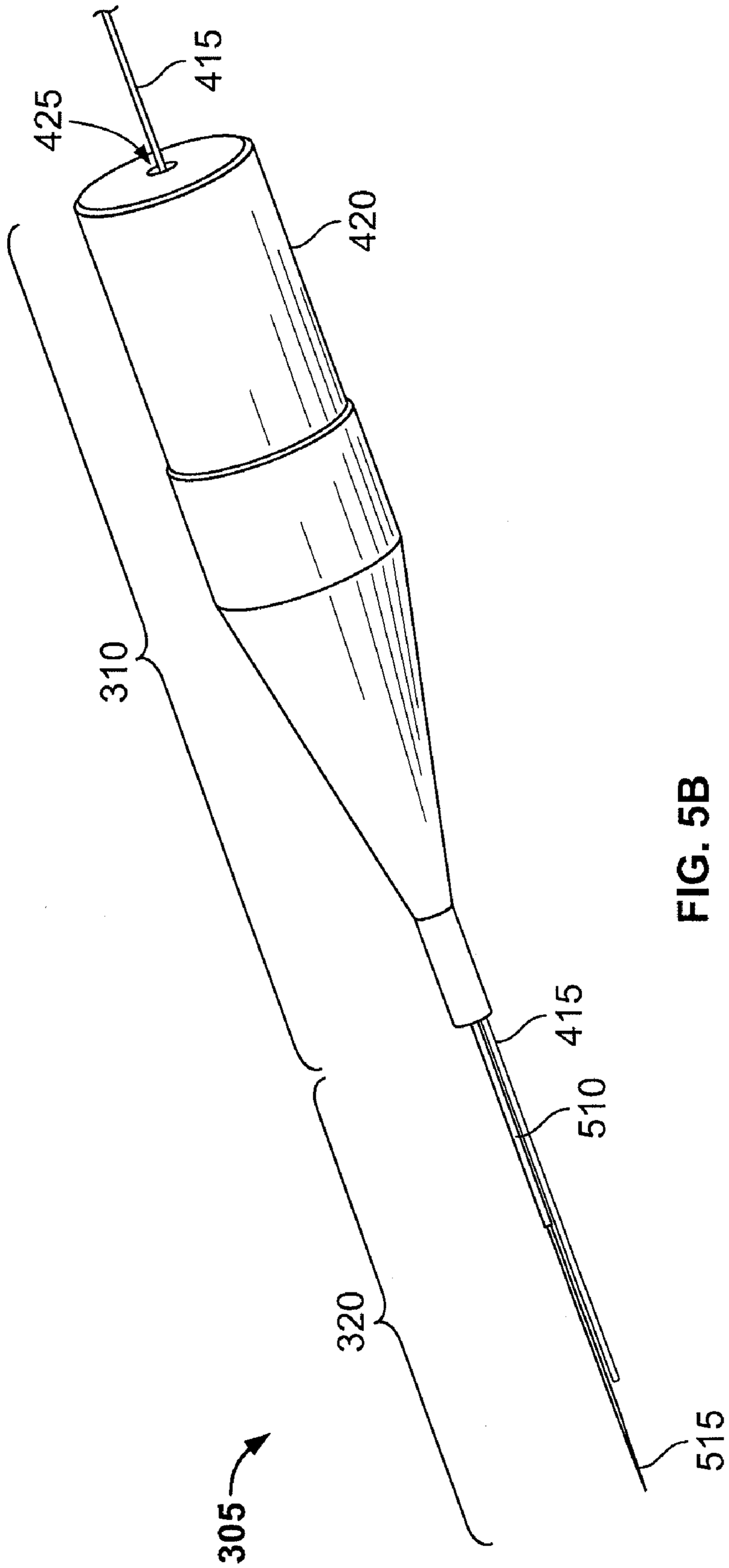

FIG. 5B

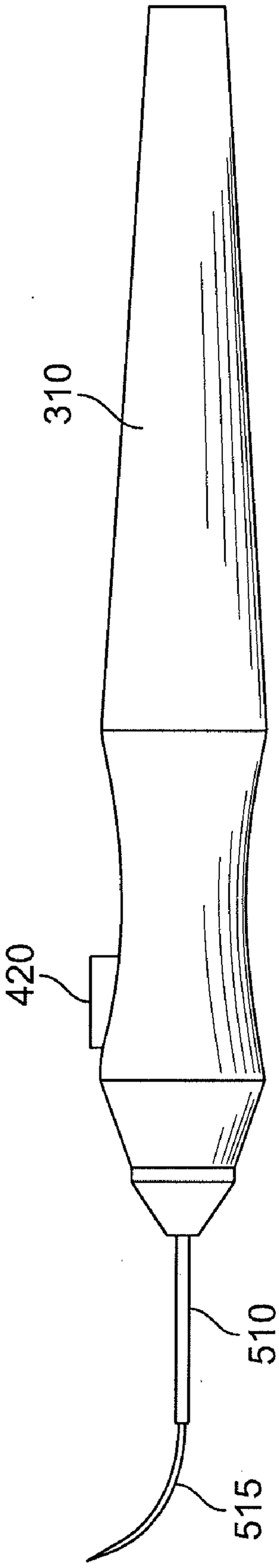

FIG. 5C

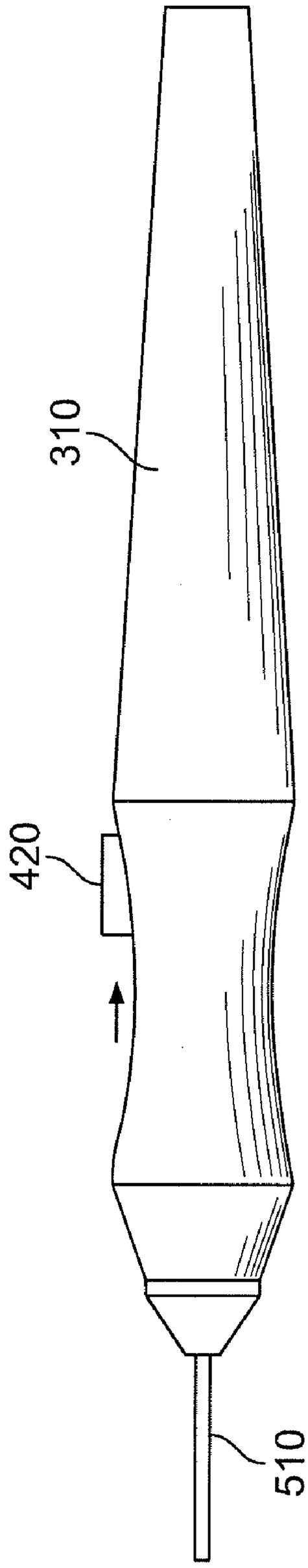

FIG. 5D

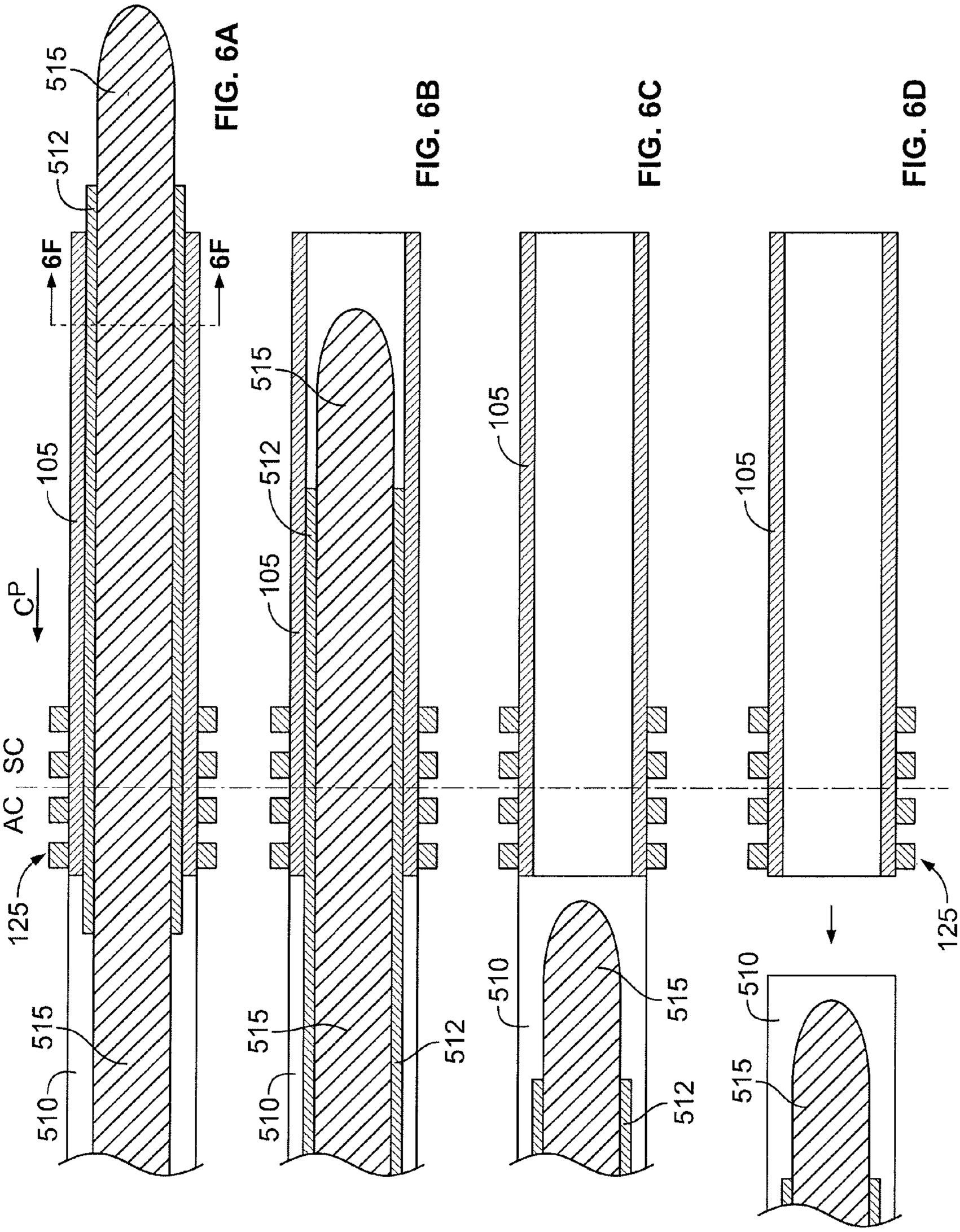

FIG. 6A

FIG. 6B

FIG. 6C

FIG. 6D

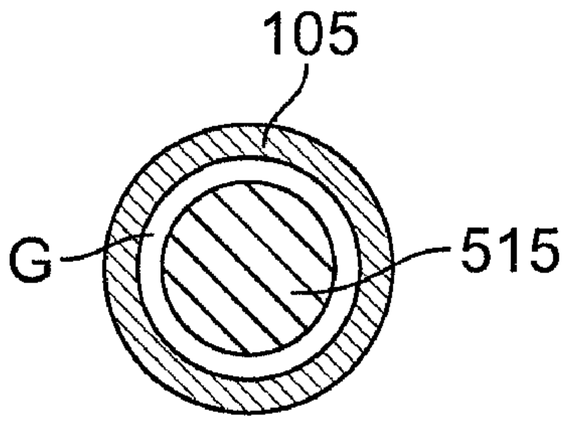

FIG. 6E

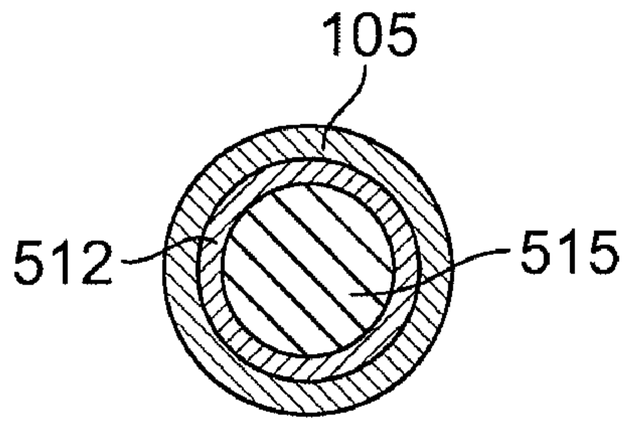

FIG. 6F

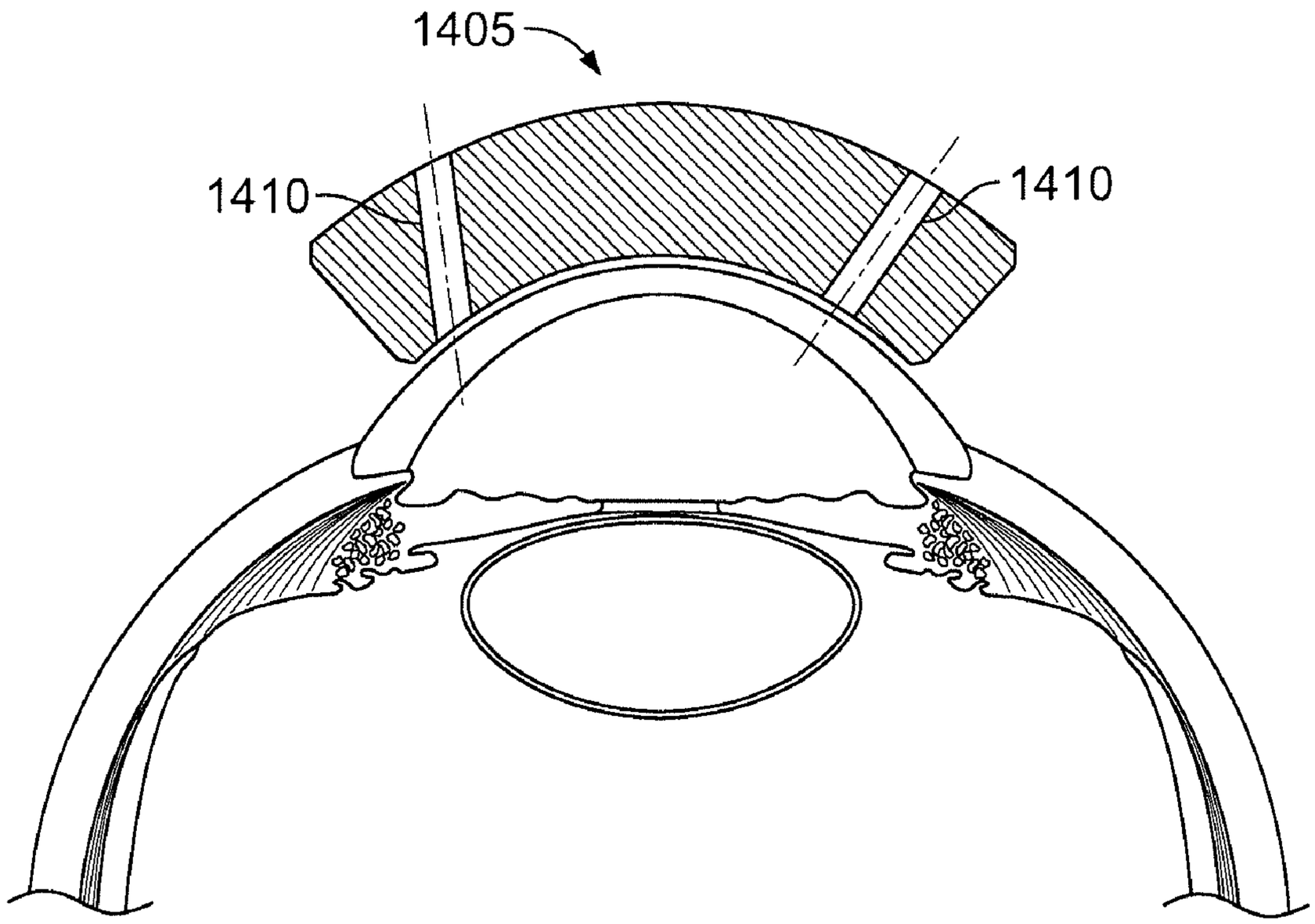

FIG. 6G

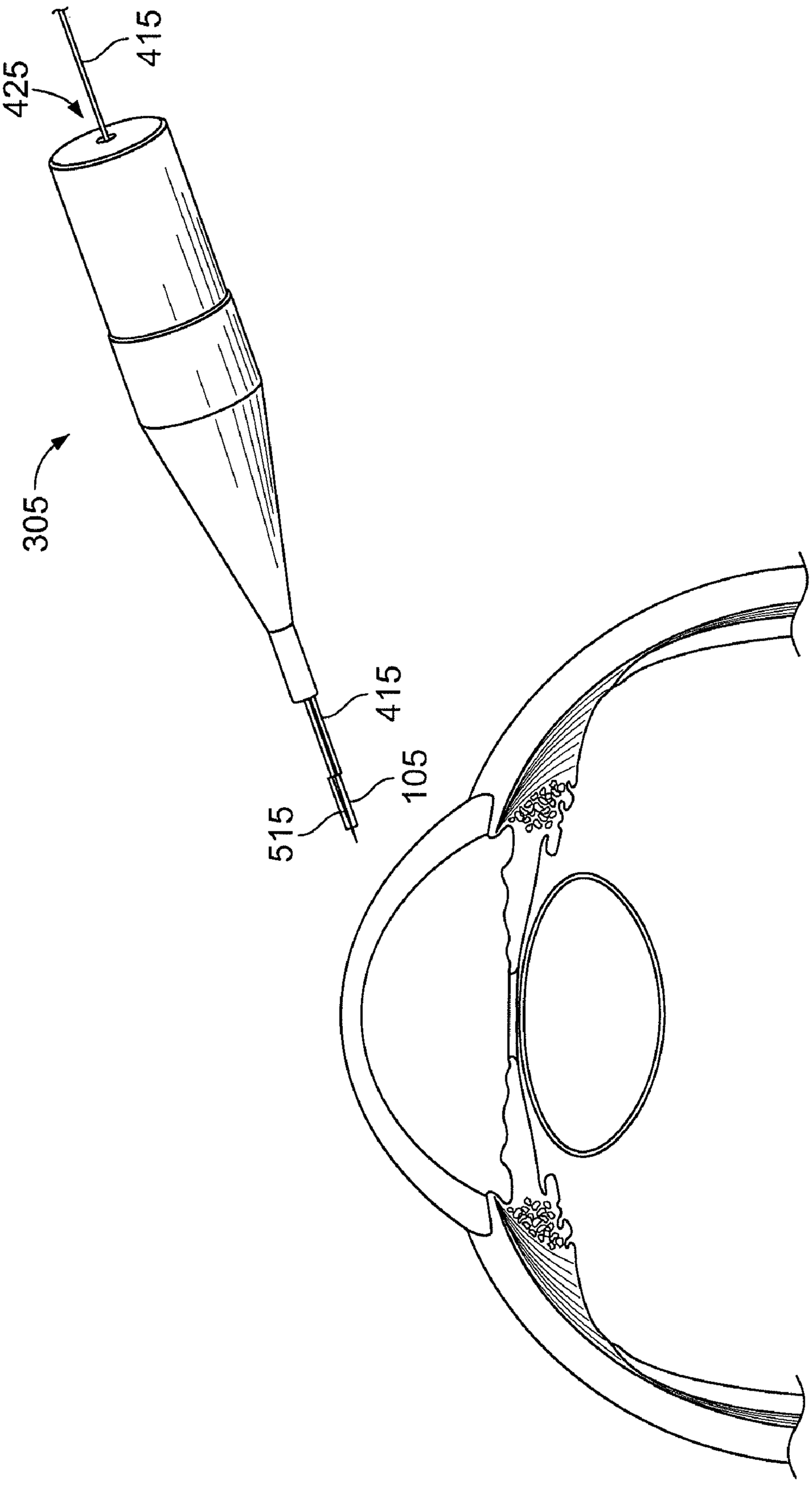

FIG. 7

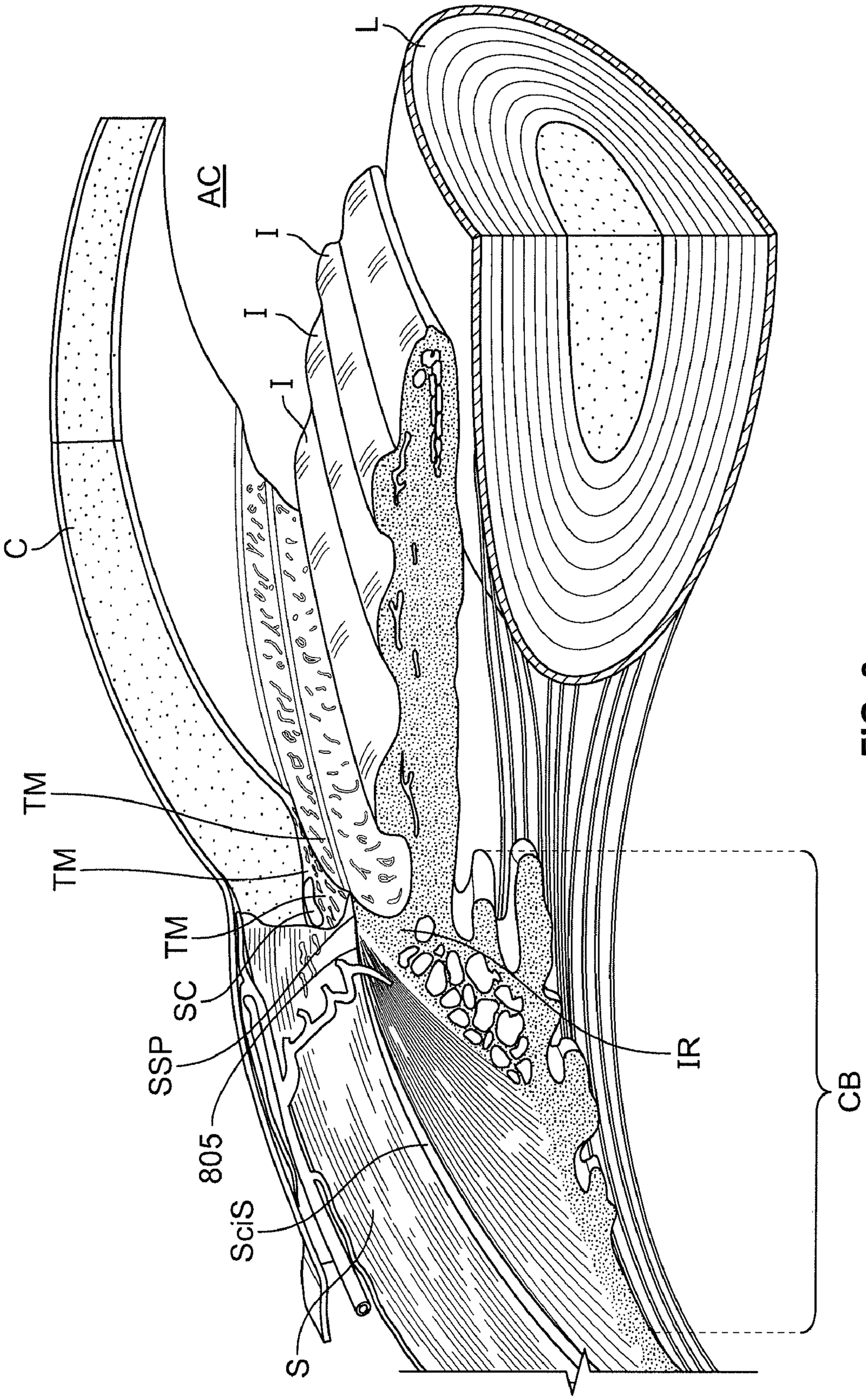

FIG. 8

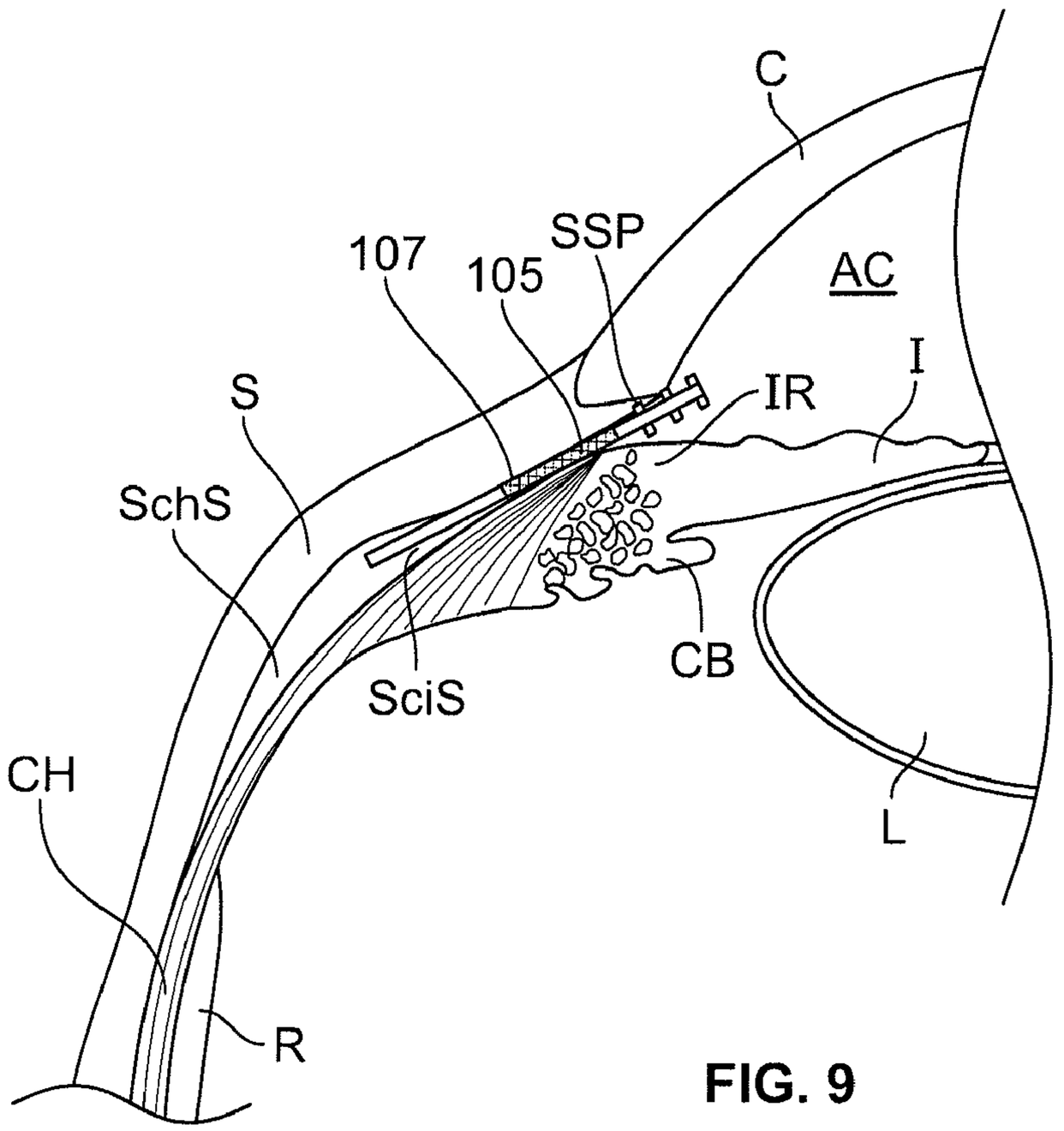

FIG. 9

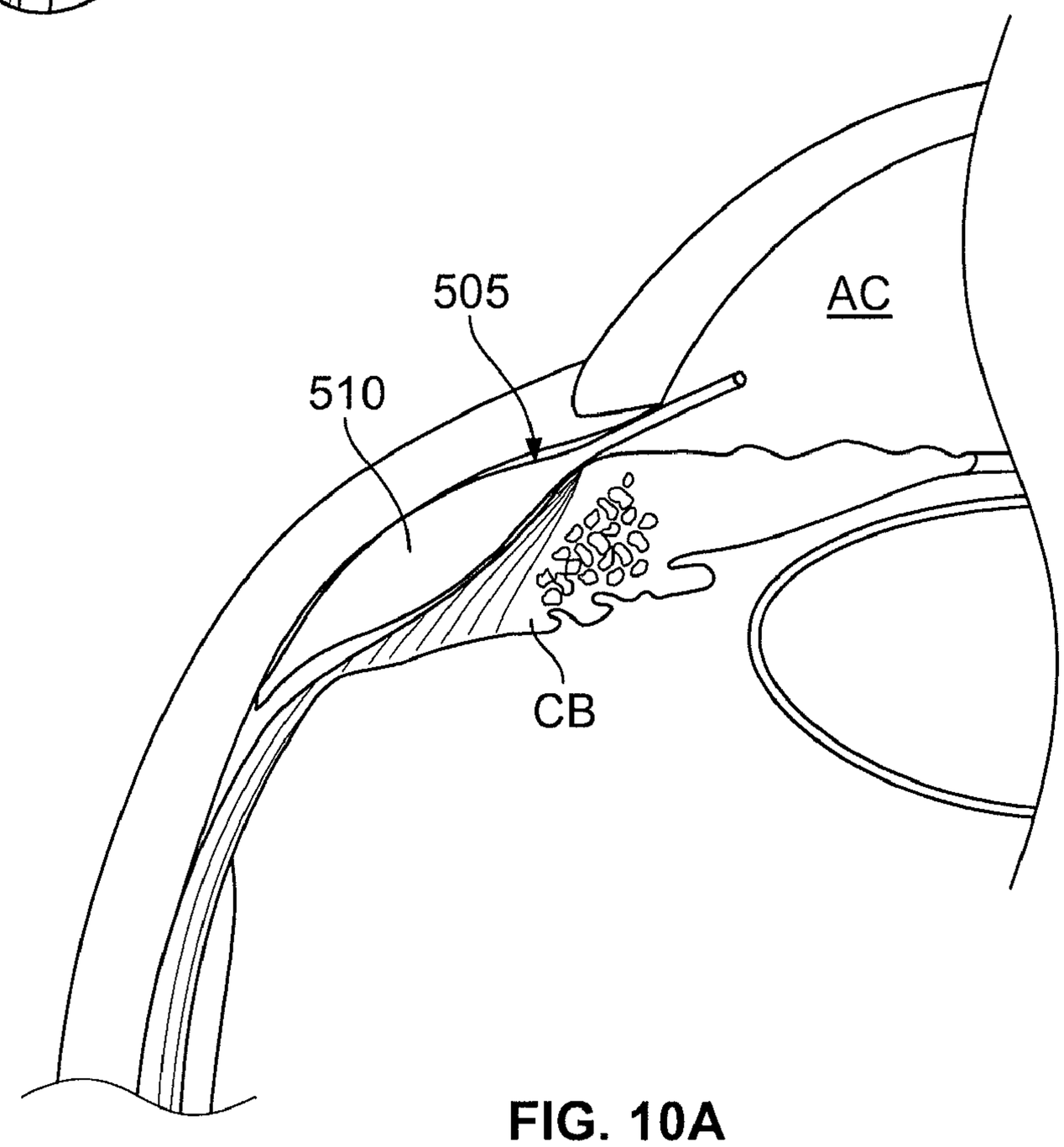

FIG. 10A

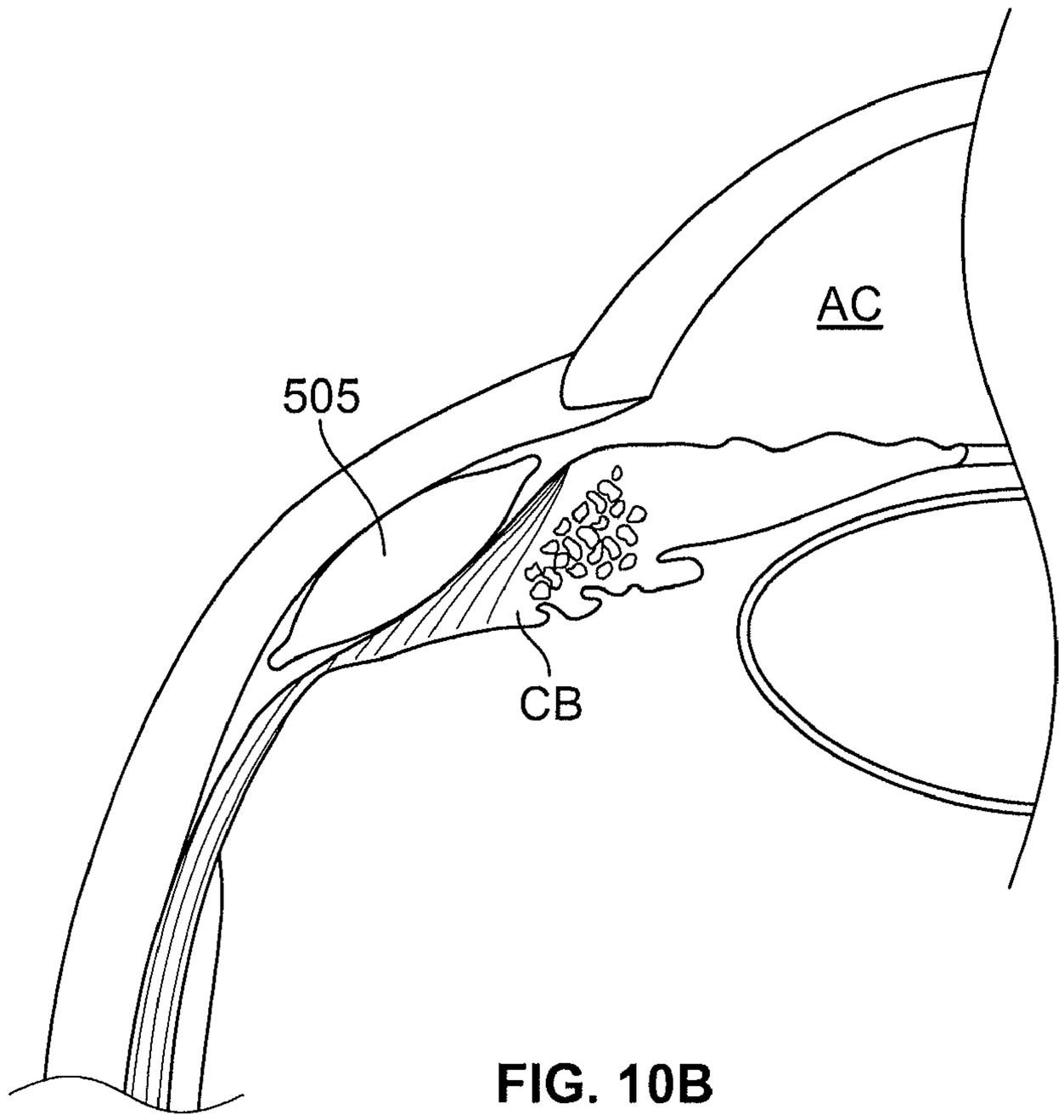

FIG. 10B

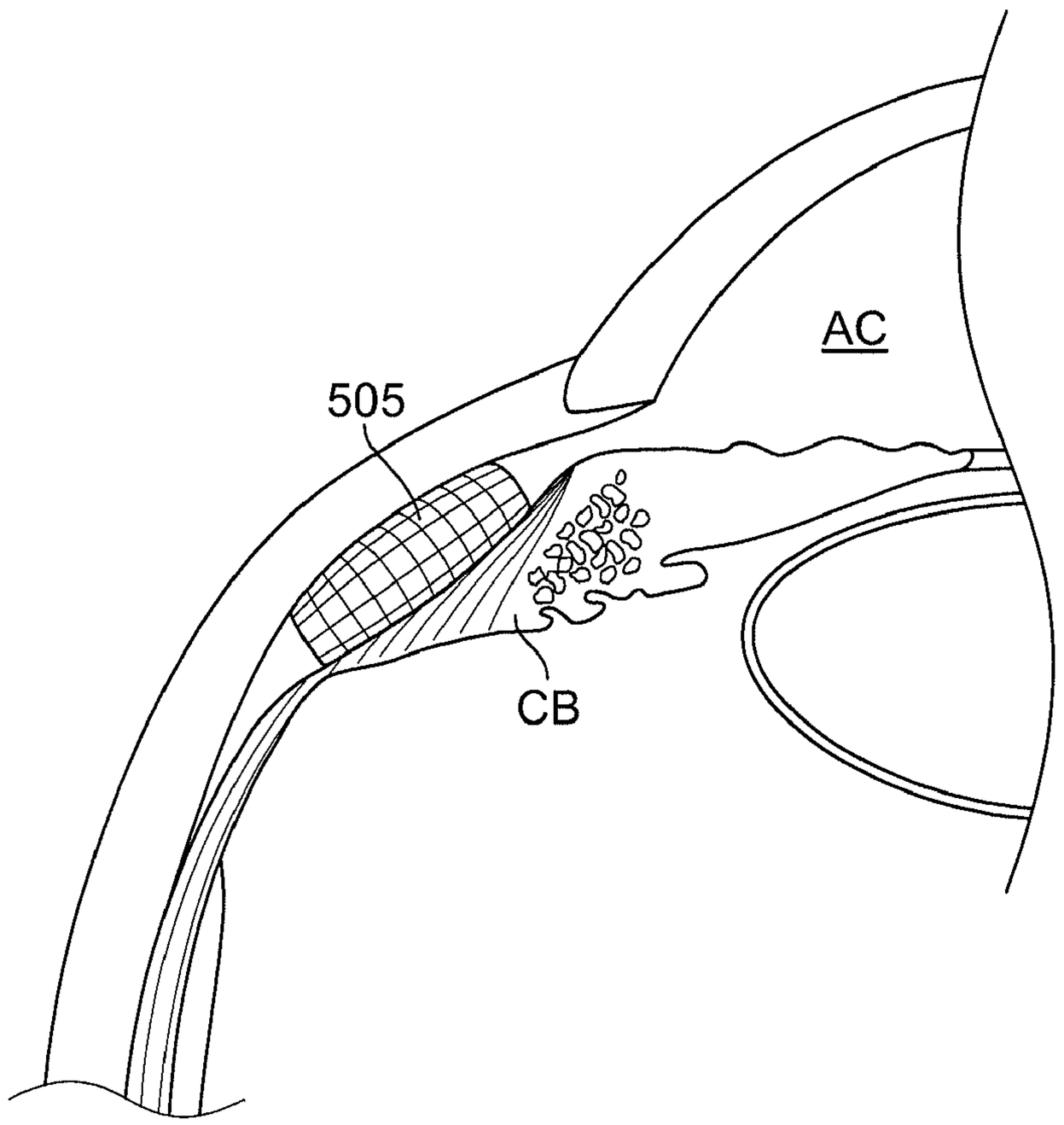

FIG. 10C

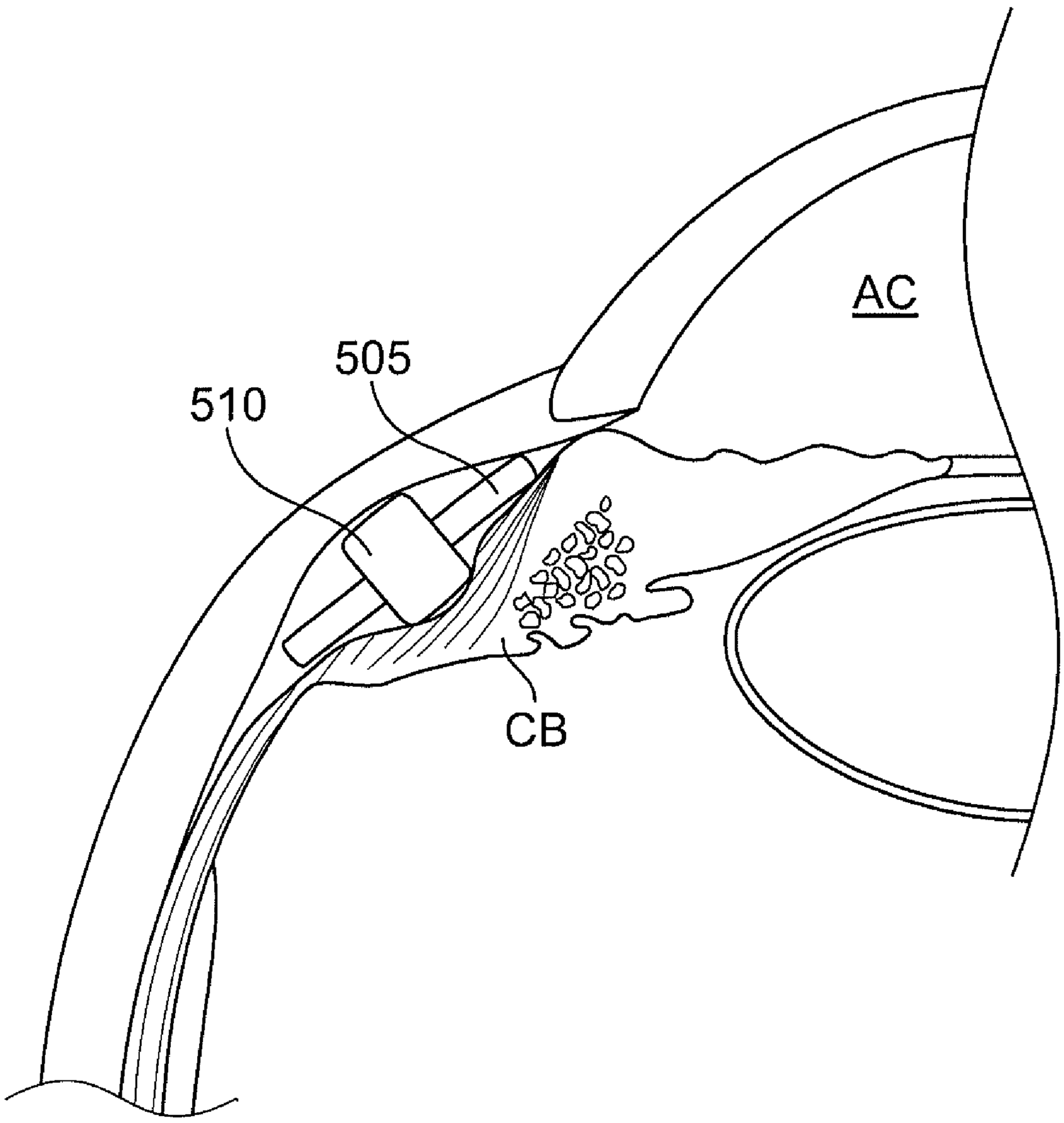

FIG. 10D

OCULAR IMPLANT WITH STIFFNESS QUALITIES, METHODS OF IMPLANTATION AND SYSTEM

REFERENCE TO PRIORITY DOCUMENTS

This application claims priority benefit under 35 U.S.C. 119(e) of co-pending U.S. Provisional Patent Application Ser. Nos. 61/147,988, filed Jan. 28, 2009, entitled "Ocular Implant with Stiffness Qualities," 61/222,054, filed Jun. 30, 2009, entitled "Ocular Device Implantation Method and System," and 61/246,017, filed Sep. 25, 2009, entitled "Ocular Implant to Reduce Aqueous Humor Production." The disclosures of the Provisional Patent Applications are hereby incorporated by reference in their entirety.

BACKGROUND

This disclosure relates generally to methods and devices for use in treating glaucoma. In particular, this disclosure relates to a device that is implantable in the eye to form a fluid passageway between the anterior chamber and the suprachoroidal space wherein the device has a relative stiffness that causes a portion of the suprachoroidal space to achieve desired shape when the implant is deployed. The implants described herein can also affect the production of aqueous humor by the ciliary body.

The mechanisms that cause glaucoma are not completely known. It is known that glaucoma results in abnormally high pressure in the eye, which leads to optic nerve damage. Over time, the increased pressure can cause damage to the optic nerve, which can lead to blindness. Treatment strategies have focused on keeping the intraocular pressure down in order to preserve as much vision as possible over the remainder of the patient's life.

Past treatment includes the use of drugs that lower intraocular pressure through various mechanisms. The glaucoma drug market is an approximate two billion dollar market. The large market is mostly due to the fact that there are not any effective surgical alternatives that are long lasting and complication-free. Unfortunately, drug treatments as well as surgical treatments that are available need much improvement, as they can cause adverse side effects and often fail to adequately control intraocular pressure. Moreover, patients are often lackadaisical in following proper drug treatment regimens, resulting in a lack of compliance and further symptom progression.

With respect to surgical procedures, one way to treat glaucoma is to implant a drainage device in the eye. The drainage device functions to drain aqueous humor from the anterior chamber and thereby reduce the intraocular pressure. The drainage device is typically implanted using an invasive surgical procedure. Pursuant to one such procedure, a flap is surgically formed in the sclera. The flap is folded back to form a small cavity and the drainage device is inserted into the eye through the flap. Such a procedure can be quite traumatic as the implants are large and can result in various adverse events such as infections and scarring, leading to the need to re-operate.

Current devices and procedures for treating glaucoma have disadvantages and only moderate success rates. The procedures are very traumatic to the eye and also require highly accurate surgical skills, such as to properly place the drainage device in a proper location. In addition, the devices that drain fluid from the anterior chamber to a subconjunctival bleb beneath a scleral flap are prone to infection, and can occlude and cease working. This can require re-operation to remove the device and place another one, or can result in further surgeries. In view of the foregoing, there is a need for improved devices and methods for the treatment of glaucoma.

SUMMARY

There is a need for improved devices and methods for the treatment of eye diseases such as glaucoma. In particular, there is a need for simplified, low profile devices for the treatment of glaucoma and other diseases using a delivery system that uses a minimally-invasive procedure.

In an embodiment described herein is an ocular implant including an elongate member having an internal lumen forming a flow pathway, at least one inflow port communicating with the flow pathway, and at least one outflow port communicating with the flow pathway. The elongate member is adapted to be positioned in the eye such that at least one inflow port communicates with the anterior chamber, at least one outflow port communicates with the suprachoroidal space to provide a fluid pathway between the anterior chamber and the suprachoroidal space when the elongate member is implanted in the eye. The elongate member has a wall material imparting a stiffness to the elongate member. The stiffness is selected such that after implantation the elongate member deforms eye tissue surrounding the suprachoroidal space forming a tented volume.

The stiffness of the elongate member can be greater than a stiffness of the eye tissue surrounding the suprachoroidal space. The elongate member can form a chord relative to a curvature of the suprachoroidal space. The eye tissue surrounding the suprachoroidal space can include an outer tissue shell having a first boundary and a first curvature and an inner tissue shell having a second boundary and a second curvature, wherein the first curvature and the second curvature form a ratio. The stiffness of the elongate member can change the ratio between the first curvature and the second curvature. The elongate member can be curved such that it intersects, but does not conform to the first or second curvatures when implanted.

The wall material can have a Young's modulus that is less than 30,000 pounds per square inch. The wall material can have a Young's modulus that is between about 30,000 pounds per square inch and 70,000 pounds per square inch. The wall material can have a Young's modulus that is approximately 200,000 pounds per square inch. The wall material can have a Young's modulus that is less than or equal to 40,000,000 pounds per square inch. The elongate member can have an inner diameter of about 0.012 inch and an outer diameter of about 0.015 inch. The elongate member can have a length in the range of about 0.250 inch to about 0.300 inch.

Also disclosed are methods of implanting an ocular device into the eye. In an embodiment, the method includes forming an incision in the cornea of the eye; loading onto a delivery device an implant having a fluid passageway and a wall material imparting a stiffness to the implant; inserting the implant loaded on the delivery device through the incision into the anterior chamber of the eye; passing the implant along a pathway from the anterior chamber into the suprachoroidal space; positioning at least a portion of the implant in the suprachoroidal space such that a first portion of the fluid passageway communicates with the anterior chamber and a second portion of the fluid passageway communicates with the suprachoroidal space to provide a fluid passageway between the suprachoroidal space and the anterior chamber; and releasing the implant from the delivery device such that the implant achieves a predetermined shape within the suprachoroidal space and forms a chord relative to a curvature of

the suprachoroidal space. The chord can be straight or the chord can be curved. The stiffness of the implant can be greater than a stiffness of adjacent eye tissue.

In another embodiment the method of treating an eye includes forming an incision in the cornea of the eye; inserting an implant through the incision into the anterior chamber of the eye wherein the implant includes a fluid passageway; passing the implant along a pathway from the anterior chamber into the suprachoroidal space; positioning the implant such that a first portion of the fluid passageway communicates with the anterior chamber and a second portion of the fluid passageway communicates with the suprachoroidal space to provide a fluid passageway between the suprachoroidal space and the anterior chamber; and applying a force on the ciliary body with the implant so as to reduce aqueous outflow from the ciliary body.

Applying a force on the ciliary body with the implant can elicit an increase in prostaglandin production by the ciliary body. Applying a force on the ciliary body with the implant can include displacing at least a portion of the ciliary body. Applying a force on the ciliary body with the implant does not necessarily displace the ciliary body.

Other features and advantages should be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional, perspective view of a portion of the eye showing the anterior and posterior chambers of the eye;

FIG. **2** is a cross-sectional view of a human eye;

FIG. **3** shows an embodiment of an implant;

FIG. **4** shows relative shapes of the implant and the suprachoroidal space;

FIG. **5**A shows an exemplary delivery system that can be used to deliver the implant into the eye;

FIG. **5**B shows another embodiment of a delivery system that can be used to deliver an implant into the eye;

FIGS. **5**C and **5**D show the delivery system of FIG. **5**B during actuation;

FIG. **6**A-**6**D show an exemplary mechanism for delivering an implant;

FIG. **6**E is a cross-sectional view of an embodiment of a delivery system;

FIG. **6**F is a cross-sectional view of the delivery system of FIG. **6**A taken along line F-F;

FIG. **6**G shows a cross-sectional view of the eye and a viewing lens;

FIG. **7** shows a schematic of the fiber optic visualization and delivery system positioned for penetration into the eye;

FIG. **8** shows an enlarged view of a portion of the anterior region of the eye in cross-section;

FIG. **9** shows the implant positioned within the suprachoroidal space;

FIGS. **10**A-**10**D show other implants that reduces aqueous humor production.

It should be appreciated that the drawings herein are exemplary only and are not meant to be to scale.

DETAILED DESCRIPTION

There is a need for improved methods and devices for the treatment of eye diseases. Disclosed herein are low profile, simplified devices that can be used in the eye for the treatment of glaucoma and other eye diseases. The devices can be placed in the eye such that the implant provides a fluid pathway for the flow or drainage of aqueous humor from the anterior chamber to the suprachoroidal space. The devices described herein are designed to enhance aqueous flow through the normal outflow system of the eye with minimal to no complications.

There is also a need for low profile, simplified delivery devices to deliver an implant that can gently and bluntly dissect between tissue margins or tissue layer boundaries, for example, between the iris root and the scleral spur or the iris root part of the ciliary body and the scleral spur into the supraciliary space and then, further on, between the sclera and the choroid into the suprachoroidal space in the eye. The devices described herein can be implanted in the eye using a delivery system that uses a minimally-invasive procedure and can penetrate certain tissues and separate tissue boundaries while avoid penetrating certain other tissues. Any of the procedures and devices described herein can be performed in conjunction with other therapeutic procedures, such as laser iridotomy, laser iridoplasty, and goniosynechialysis (a cyclodialysis procedure).

Described herein also are devices, systems and methods for the treatment of eye diseases such as glaucoma that cause a reduction in aqueous humor production. Aqueous humor is generally produced by ciliary body cells. Implanting a device that can impose a force such as a radial force on structures in the eye such as the ciliary body aqueous humor production by these cells can be reduced resulting in a decrease in intraocular pressure.

FIG. **1** is a cross-sectional, perspective view of a portion of the eye showing the anterior and posterior chambers of the eye. A schematic representation of an implant **105** is positioned inside the eye such that a proximal end **110** is located in the anterior chamber **115** and a distal end **120** extends to a region of the eye that is between the ciliary body and the sclera. Alternatively, the distal end **120** can extend to a region of the eye that is posterior to the ciliary body, such as between the choroid and the sclera. The suprachoroidal space (sometimes referred to as the perichoroidal space) can include the region between the sclera and the choroid. The suprachoroidal space can also include the region between the sclera and the ciliary body. In this regard, the region of the suprachoroidal space between the sclera and the ciliary body may sometimes be referred to as the supraciliary space. The implant described herein is not necessarily positioned between the choroid and the sclera. The implant **105** can be positioned at least partially between the ciliary body and the sclera or it can be at least partially positioned between the sclera and the choroid. In any event, the implant **105** can provide a fluid pathway for flow of aqueous humor through or along the implant between the anterior chamber and the suprachoroidal space.

In an embodiment, the implant **105** can be an elongate element having one or more internal lumens through which aqueous humor can flow from the anterior chamber **115** into the suprachoroidal space. The implant **105** can have a substantially uniform diameter along its entire length, although the shape of the implant **105** can vary along its length (either before or after insertion of the implant), as described below. Moreover, the implant **105** can have various cross-sectional shapes (such as circular, oval or rectangular shape) and can vary in cross-sectional shape moving along its length. The cross-sectional shape can be selected to facilitate easy insertion into the eye. The following applications describe exemplary implants and are incorporated by reference in their entirety: U.S. Patent Publication Nos. 2007-0191863 and 2009-0182421.

At least a portion of the implant can be formed of a structure having a stiffness that causes the implant **105** to form a chord (either straight, curved, or curvlinear) relative to the natural-state curvature of the suprachoroidal space, as described in detail below. That is, the implant can define a line that intersects at least two points along a curve that conforms to the natural curvature of the suprachoroidal space if the implant were not present. The implant **105** can have a stiffness that is greater than the stiffness of adjacent eye tissue (e.g., the choroid and the sclera or the ciliary body and sclera) such that the implant **105** deforms the eye tissue and forms a chord relative to the curvature of the suprachoroidal space when implanted in the eye. The presence of the implant **105** can cause the suprachoroidal space to achieve a geometry that produces a tented volume within the suprachoroidal space.

Eye Anatomy and Glaucoma

FIG. **2** is a cross-sectional view of a portion of the human eye. The eye is generally spherical and is covered on the outside by the sclera S. The retina lines the inside posterior half of the eye. The retina registers the light and sends signals to the brain via the optic nerve. The bulk of the eye is filled and supported by the vitreous body, a clear, jelly-like substance. The elastic lens L is located near the front of the eye. The lens L provides adjustment of focus and is suspended within a capsular bag from the ciliary body CB, which contains the muscles that change the focal length of the lens. A volume in front of the lens L is divided into two by the iris I, which controls the aperture of the lens and the amount of light striking the retina. The pupil is a hole in the center of the iris I through which light passes. The volume between the iris I and the lens L is the posterior chamber PC. The volume between the iris I and the cornea is the anterior chamber AC. Both chambers are filled with a clear liquid known as aqueous humor.

The ciliary body CB continuously forms aqueous humor in the posterior chamber PC by secretion from the blood vessels. The aqueous humor flows around the lens L and iris I into the anterior chamber and exits the eye through the trabecular meshwork TM, a sieve-like structure situated at the corner of the iris I and the wall of the eye (the corner is known as the iridocorneal angle). Some of the aqueous humor filters through the trabecular meshwork near the iris root into Schlemm's canal, a small channel that drains into the ocular veins. A smaller portion rejoins the venous circulation after passing through the ciliary body and eventually through the sclera (the uveoscleral route).

Glaucoma is a disease wherein the aqueous humor builds up within the eye. In a healthy eye, the ciliary processes secrete aqueous humor, which then passes through the angle between the cornea and the iris. Glaucoma appears to be the result of clogging in the trabecular meshwork. The clogging can be caused by the exfoliation of cells or other debris. When the aqueous humor does not drain properly from the clogged meshwork, it builds up and causes increased pressure in the eye, particularly on the blood vessels that lead to the optic nerve. The high pressure on the blood vessels can result in death of retinal ganglion cells and eventual blindness.

Closed angle (acute) glaucoma can occur in people who were born with a narrow angle between the iris and the cornea (the anterior chamber angle). This is more common in people who are farsighted (they see objects in the distance better than those which are close up). The iris can slip forward and suddenly close off the exit of aqueous humor, and a sudden increase in pressure within the eye follows.

Open angle (chronic) glaucoma is by far the most common type of glaucoma. In open angle glaucoma, the iris does not block the drainage angle as it does in acute glaucoma. Instead, the fluid outlet channels within the wall of the eye gradually narrow with time. The disease usually affects both eyes, and over a period of years the consistently elevated pressure slowly damages the optic nerve.

Implant

FIG. **3** shows a first embodiment of an implant **105**. The implant **105** can be an elongate member having a proximal end, a distal end, and a structure that permits fluid (such as aqueous humor) to flow along the length of the implant such as through or around the implant from the anterior chamber to the suprachoroidal space. As mentioned above, the proximal end of the implant **105** is positioned in the anterior chamber and the distal end of the implant can extend to a region of the eye that is between the ciliary body and the sclera. The distal end of the implant can also extend to a region of the eye that is posterior to the ciliary body, such as between the choroid and the sclera. The suprachoroidal space can include the region between the sclera and the choroid as well as the region between the sclera and the ciliary body. The implant **105** can provide a fluid pathway for communication of aqueous humor between the anterior chamber and the suprachoroidal space.

In the embodiment of FIG. **3**, the implant **105** can include at least one internal lumen **110** having at least one opening **115** for ingress of fluid (such as aqueous humor from the anterior chamber) and at least one opening **120** for egress of fluid into the suprachoroidal space. The implant **105** can include various arrangements of openings **125** that communicate with the lumen(s) **110**. The openings **125** in the implant **105** can be filled with a material or mixture of materials, such as a sponge material, to prevent unwanted tissue in-growth into the openings **125** when the implant **105** is positioned in the eye. The sponge material can also be filled with a drug or other material that leaches into the eye over time upon implantation. During delivery of the implant **105**, the openings **125** can be positioned so as to align with predetermined anatomical structures of the eye. For example, one or more openings **125** can align with the suprachoroidal space to permit the flow of aqueous humor into the suprachoroidal space, while another set of openings **125** can align with structures proximal to the suprachoroidal space, such as structures in the ciliary body or the anterior chamber of the eye.

The internal lumen **110** can serve as a passageway for the flow of aqueous humor through the implant **105** directly from the anterior chamber to the suprachoroidal space. In addition, the internal lumen **110** can be used to mount the implant **105** onto a delivery system, as described below. The internal lumen **110** can also be used as a pathway for flowing irrigation fluid into the eye generally for flushing or to maintain pressure in the anterior chamber. In the embodiment of FIG. **3**, the implant **105** can have a substantially uniform diameter along its entire length, although the shape of the implant **105** can vary along its length (either before or after insertion of the implant). Moreover, the implant **105** can have various cross-sectional shapes (such as a, circular, oval or rectangular shape) and can vary in cross-sectional shape moving along its length. The cross-sectional shape can be selected to facilitate easy insertion into the eye.

FIG. **3** shows an embodiment of the implant **105** having a tubular or partially tubular structure. The implant **105** has a proximal region **305** and a distal region **315**. In an embodiment, the proximal region **305** has a generally tubular shape with a collar **325**. The collar **325** is shown in phantom lines to indicate that the collar **325** is optional. The collar **325** can be formed of the same material as the rest of the implant **105** or a different material. The collar **325** can have various shapes

including a funnel shape such that the collar **325** provides a relatively wide opening that communicates with the internal lumen of the implant **105**.

As illustrated schematically in FIG. **4**, when implanted in the eye the implant **105** can form a dissection plane within or near the suprachoroidal space. The dissection plane can be straight or it can be curved as the dissection plane is being formed. At least a portion of the suprachoroidal space can be described as the space between two curved shells: a first, outer shell including the scleral tissue and a second, inner shell including the choroidal tissue. Alternatively, the first, outer shell can include the scleral tissue and the second, inner shell can include the ciliary body tissue. The shells can abut one another in that the inner surface of the sclera abuts the outer surface of the choroid (or ciliary body) with the suprachoroidal space being a virtual space that exists when the sclera is separated from the choroid (or ciliary body). The sclera has a tougher texture than the choroid or ciliary body. The implant **105** can have a stiffness such that its presence in or near the suprachoroidal space can increase or decrease ratios of curvature of one or both of the shells by pushing against the tough outer shell and/or the fragile inner shell. If the dissection plane is curved, the dissection plane can have a curvature that will follow a dissecting wire that performs the dissection or that is governed by the shape and/or stiffness of the implant positioned in the dissection plane. The curvature can be different from the curvature of the suprachoroidal space when the implant is implanted in the eye. Thus, the implant can form a straight or curved chord relative to the natural curvature of the suprachoroidal space if the implant were not present in the suprachoroidal space.

FIG. **4** shows a curve S (in solid line) that represents the natural curvature of the suprachoroidal space when the implant is not present. The implant **105** (represented by a dashed line) can be a straight implant (as shown in FIG. **4**) or a curved implant that intersects the natural curvature S but does not conform to the natural curvature when implanted. The implant **105** can have a relative stiffness such that, when implanted, the implant **105** can deform at least a portion of the tissue adjacent the suprachoroidal space to take on a shape that is different than the natural curvature. In this manner, the implant **105** can form a tent or volume between the tissue boundaries (formed by the sclera and choroid) of the suprachoroidal space that does not exist naturally.

The implant **105** can have structural properties that cause the implant to interfere with and/or resist the natural curvature of the suprachoroidal space when implanted in the eye. In this regard, the implant **105** can have an effective or extrinsic Young's modulus (relative to the Young's modulus of the tissue boundary of the suprachoroidal space) that causes the implant to interfere with and locally change the curvature of the boundary between the sclera and the choroid when implanted in the eye. The effective modulus of the implant can depend upon the intrinsic modulus (or Young's modulus in this case), the shape and thickness of the implant. As mentioned above, the implant **105**, when implanted, does not necessarily extend into a region of the suprachoroidal space that is between the sclera and the choroid. The implant can be positioned between the ciliary body and the sclera (within the supraciliary space) but still communicate with the suprachoroidal space. The implant **105** can be made of a material that has the requisite stiffness, or the implant can have structural properties, such as thickness or length, that achieve the requisite stiffness and deformation of the normal curvature of the sclera-suprachoroid boundary.

In an embodiment, a portion of the implant can be made of a material that has a Young's modulus that is less than 3,000 pounds per square inch (PSI). In another embodiment, the Young's modulus is greater than 30,000 psi. In another embodiment, the Young's modulus is between 30,000 psi and 70,000 psi. In another embodiment, the Young's modulus is 70,000 psi to 200,000 psi. In another embodiment, the Young's modulus is in the range of 100,000 psi to 200,000 psi. In another embodiment, the Young's modulus is approximately 200,000 psi. In another embodiment, the Young's modulus is less than or equal to 40,000,000 psi. It should be appreciated that the aforementioned values are exemplary and non-limiting. As mentioned above, the effective modulus of the implant depends upon intrinsic modulus (or Young's modulus in this case), shape and thickness of the implant. Therefore, if the modulus of the implant is below 30,000 psi, the dimensions of the implant such as material shape and thickness can be sufficient to maintain the effective modulus of the implant in order to overcome the bending modulus of one or more of the surrounding tissues.

In an embodiment, the implant **105** can have a column strength sufficient to permit the implant **105** to be inserted into suprachoroidal space such that the distal tip of the implant **105** tunnels through the eye tissue (such as the ciliary body) without structural collapse or structural degradation of the implant **105**. In addition, the surface of the inner lumen can be sufficiently smooth relative to the delivery device (described in detail below) to permit the implant **105** to slide off of the delivery device during the delivery process. In an embodiment, the column strength can be sufficient to permit the implant to tunnel through the eye tissue into the suprachoroidal space without any structural support from an additional structure such as a delivery device.

The implant **105** can be made of various materials, including, for example, polyimide, Nitinol, platinum, stainless steel, molybdenum, or any other suitable polymer, metal, metal alloy, or ceramic biocompatible material or combinations thereof. Other materials of manufacture or materials with which the shunt can be coated or manufactured entirely include Silicone, PTFE, ePTFE, differential fluoropolymer, FEP, FEP laminated into nodes of ePTFE, silver coatings (such as via a CVD process), gold, prolene/polyolefins, polypropylene, poly(methyl methacrylate) (PMMA), acrylic, PolyEthylene Terephthalate (PET), Polyethylene (PE), PLLA, and parylene. The implant **105** can be reinforced with polymer, Nitinol, or stainless steel braid or coiling or can be a co-extruded or laminated tube with one or more materials that provide acceptable flexibility and hoop strength for adequate lumen support and drainage through the lumen. The shunt can alternately be manufactured of nylon (polyamide), PEEK, polysulfone, polyamideimides (PAI), polyether block amides (Pebax), polyurethanes, thermoplastic elastomers (Kraton, etc), and liquid crystal polymers.

Any of the embodiments of the implant **105** described herein can be coated on its inner or outer surface with one or more drugs or other materials, wherein the drug or material maintains the patency of the lumen or encourages in-growth of tissue to assist with retention of the implant within the eye or to prevent leakage around the implant. The drug can also be used for disease treatment. The implant can also be coated on its inner or outer surface with a therapeutic agent, such as a steroid, an antibiotic, an anti-inflammatory agent, an anti-coagulant, an anti-glaucomatous agent, an anti-proliferative, or any combination thereof. The drug or therapeutic agent can be applied in a number of ways as is known in the art. Also the drug can be embedded in another polymer (nonabsorbable or bioabsorbable) that is coated on the implant.

The implant can also be coated or layered with a material that expands outward once the shunt has been placed in the

eye. The expanded material fills any voids that are positioned around the shunt. Such materials include, for example, hydrogels, foams, lyophilized collagen, or any material that gels, swells, or otherwise expands upon contact with body fluids.

The implant can also be covered or coated with a material (such as polyester, ePTFE (also known as GORETEX®), PTFE that provides a surface to promote healing of the shunt into the surrounding tissue. In order to maintain a low profile, well-known sputtering techniques can be employed to coat the shunt. Such a low profile coating would accomplish a possible goal of preventing migration while still allowing easy removal if desired.

In an embodiment, the implant can have an inner diameter in the range of about 0.002" to about 0.050", an outer diameter in the range of about 0.006" to about 0.100", and a length in the range of about 0.100" to about 1.50". In another embodiment, the implant has an inner diameter in the range of about 0.008" to about 0.025". In another embodiment, the implant has an inner diameter in the range of about 0.010" to about 0.012". In another embodiment, the implant has an outer diameter in the range of about 0.012" to about 0.075". In another embodiment, the implant has an outer diameter in the range of about 0.025" to about 0.050". In another embodiment, the implant has a length in the range of about 0.125" to about 0.75". In another embodiment, the implant has a length in the range of about 0.25" to about 0.50". In another embodiment, the implant has an inner diameter of about 0.012", an outer diameter of about 0.020" and a length of about 0.25".

The implant can also have visual markers along its length to assist the user in positioning the desired portion of the implant within the anterior chamber. Further, the implant **105** and/or delivery system can employ alignment marks, tabs, slots or other features that allow the user to know alignment of the implant with respect to the delivery device. The implant **105** can include one or more features that aid in properly positioning the implant **105** in the eye. For example, the implant can have one or more visual, tomographic, echogenic, or radiopaque markers that can be used to aid in placement using any of the devices referenced above tuned to its applicable marker system. In using the markers to properly place the implant, the implant is inserted in the suprachoroidal space, until the marker is aligned with a relevant anatomic structure, for example, visually identifying a marker on the anterior chamber portion of the implant that aligns with the trabecular meshwork, or scleral spur, such that an appropriate length of the implant remains in the anterior chamber. Under ultrasound, an echogenic marker can signal the placement of the device within the suprachoroidal space. Any marker can be placed anywhere on the device to provide sensory feedback to the user on real-time placement, confirmation of placement or during patient follow up. Other structural features are described below.

Implant Delivery System

In an embodiment, a delivery system is used to deliver an implant **105** into the eye such that the implant **105** provides fluid communication between the anterior chamber and the suprachoroidal space. FIG. **5**A shows an embodiment of a delivery system **305** that can be used to deliver the implant **105** into the eye. FIG. **5**B shows another embodiment of a delivery system **305** that can be used to deliver the implant **105** into the eye. It should be appreciated that these delivery systems **305** are for illustration and that variations in the structure, shape and actuation of the delivery system **305** are possible.

The delivery system **305** generally includes a proximal handle component **310** and a distal delivery component **320**. The proximal handle component **310** can include an actuator **420** to control the release of an implant from the delivery component **320** into the target location in the eye. The proximal handle component **310** also can include a channel **425** for insertion of an internal visualization system, such as a fiber optic image bundle **415**, as in the embodiment of FIG. **5**B. Such a delivery system having an internal visualization system need not be used in conjunction with a gonioscope or viewing lens.

The delivery component **320** includes an elongate applier **515** that can insert longitudinally through the internal lumen of the implant **105** and a sheath **510** that can be positioned axially over the applier **515**. The sheath **510** aids in the release of the implant **105** from the delivery component **320** into the target location in the eye. As best shown in FIGS. **5**C and **5**D, the actuator **420** can be used to control the applier **515** and/or the sheath **510**. For example, the sheath **510** can be urged in a distal direction relative to the applier **515** to push the implant **105** off the distal end of the applier **515**. Alternately, the sheath **510** can be fixed relative to the handle component **310**. In this embodiment, the sheath **510** can act as a stopper that impedes the implant **105** from moving in a proximal direction as the applier **515** is withdrawn proximally from the implant **105** upon actuation of the actuator **420**. In a first state shown in FIG. **5**C, the applier **515** can be extended distally relative to the sheath **310**. Movement of the actuator **420**, such as in the proximal direction, can cause the applier **515** to slide proximally into the sheath **510** as shown in FIG. **5**D. This effectively pushes the implant **105** off the distal end of the applier **515** and releases the implant **105** in a controlled fashion such that the target positioning of the implant **105** within the suprachoroidal space is maintained. The delivery device **305** can also incorporate a delivery channel within which the implant **105** can reside and a pusher that can push the implant out from the delivery channel during implantation.

Internal Implant Retention Layer

The outer diameter of the applier **515** is generally smaller than the inner diameter of the implant **105** (i.e. the fluid channel) such that the implant **105** can be loaded onto the applier **515**. In some instances, the outer diameter of the applier **515** can be significantly smaller thereby creating a gap G between the applier **515** and the implant **105** (see FIG. **6**E). This gap G leaves room for adding a retention layer **512** or a retention coating to the delivery component **320** (see FIG. **6**F). The retention layer **512** can retain the implant **105** on the applier **515** during blunt dissection and implantation to prevent the implant **105** from inadvertently falling off the applier **515** until it is delivered to the desired target location within the eye. An advantage of a retention layer **512** between the implant and the applier is the very low profile of the delivery system **305** and a user's improved ability to visualize each step of implantation. Retention layers added externally around the implant, in contrast, significantly increase the profile of the delivery device and negatively impact the user's ability to visualize the steps of delivery. External retention layers can also increase the size of the incision needed to insert the delivery device.

FIGS. **6**A-**6**D show cross-sectional schematic views of an implant **105** mounted on a delivery portion **320** inserted from the anterior chamber into the suprachoroidal space. The figures show an implant **105** mounted on the end of an applier **515**, a sheath **510** sized and shaped to receive or abut a portion of the proximal end **125** of the implant **105**, and a retention layer **512** providing an interference fit between the implant **105** and the applier **515**. In this embodiment upon actuation the applier **515** slides in the proximal direction (arrow P) into the sheath **510**. The proximal end **125** of the implant **105** abuts the distal edge of the sheath **510** to prevent the implant **105**

from sliding in the proximal direction. This effectively pushes the implant **105** off the distal end of the applier **515** and controllably releases the implant **105** into the suprachoroidal space SC. The retention layer **512** moves with the applier **515** such that the applier **515** and retention layer **512** are fully withdrawn into the sheath **510**. It should be appreciated that the sheath **510** can also advanced distally over the applier **515** upon actuation to deliver the implant **105** into the suprachoroidal space.

The retention layer **512** can include, for example, a sleeve such as a shrink-to-fit tube that can be inserted over the applier **515**. The retention layer **512** can also be inserted through the fluid pathway of the implant **105**. The retention layer **512** can also include a coating of material, for example on the outer diameter of the applier **515** or on the inner diameter of the implant **105**. The retention layer **512** can also serve to prevent tissue from jamming into the gap G between the applier **515** and implant **105**, for example during insertion of the device through the iris root or the ciliary body.

The retention layer **512** can be a variety of materials. In an embodiment, the retention layer **512** can be a generally soft, elastomeric, compliant polymer. For example, the material of the retention layer **512** can include silicone, thermoplastic elastomers (HYTREL, RATON, PEBAX), certain polyolefin or polyolefin blends, elastomeric alloys, polyurethanes, thermoplastic copolyester, polyether block amides, polyamides (such as Nylon), block copolymer polyurethanes (such as LYCRA). Some other exemplary materials include fluoropolymer (such as FEP and PVDF), FEP laminated into nodes of ePTFE, acrylic, low glass transition temperature acrylics, and hydrogels. It should also be appreciated that stiffer polymers can be made to be more compliant by incorporating air or void volumes into their bulk, for example, PTFE and expanded PTFE.

Dissection Dynamics of Applier

As described above, the delivery component **320** can include an elongate applier **515**. The shape, structure, materials and material properties of the applier **515** are selected to optimize the gentle, blunt dissection between the tissue boundaries adjacent to the inner wall of the sclera and formation of the suprachoroidal space. The applier **515** can have a cross-sectional size and shape that complements the cross-sectional shape of the internal lumen of the implant **105** through which the applier **515** extends when the implant **105** is loaded thereon.

A variety of parameters including the shape, material, material properties, diameter, flexibility, compliance, pre-curvature and tip shape of the applier **515** can impact the performance of the applier **515** during gentle, blunt tissue dissection. The applier **515** desirably penetrates certain tissues while avoids penetration of other tissues. For example, it is desirable that the applier **515** be capable of penetrating the iris root or the ciliary body. The same applier **515** would beneficially be incapable of penetrating the scleral spur or inner wall of the sclera such that it can gently dissect between the tissue boundaries adjacent to the inner wall of the sclera.

The shape of the applier **515** along its long axis can be straight (as shown in FIG. **5**B) or it can be can be curved along all or a portion of its length (as shown in FIG. **5**A) in order to facilitate proper placement. In the case of the curved applier **515**, the radius of curvature can vary. For example, the applier **515** can have a radius of curvature of 3 mm to 50 mm and the curve can cover from 0 degrees to 180 degrees. In one embodiment, the applier **515** has a radius of curvature that corresponds to or complements the radius of curvature of a region of the eye, such as the inner wall of the sclera. For example, the radius of curvature can be approximately 11-12 mm. Moreover, the radius of curvature can vary moving along the length of the applier **515**. There can also be means to vary the radius of curvature of portions of the applier **515** during placement.

The distal tip shape of the applier **515** can play a part in whether or not the applier **515** penetrates certain tissues. For example, the scleral wall is a tougher tissue than the ciliary body or the iris root and generally requires a sharp-tipped applier in order to be penetrated. The distal tip of the applier **515** can be sharp enough to penetrate the iris root or the ciliary body, but not so sharp (or sufficiently dull) so as not to easily penetrate the inner wall of the sclera. The tip shape of the applier **515** can vary. The distal tip of the applier **515** described herein can have a broad angle tip. The tip shape can be symmetrical relative to a central, longitudinal axis of the applier, such as a hemispheric tip, blunt-tipped cone, rounded-off cone tip. The tip shape can also be asymmetrical such as a shovel or spade shape tip. In an embodiment the applier **515** has a blunt tip. The blunt or atraumatic tip shape aids in the gentle dissection between tissues, such as the sclera and the ciliary body and the sclera and the choroid.

The distal tip of the applier **515** can also be coated to reduce friction during dissection. In an embodiment, the distal tip of the applier **515** is coated with a hydrophilic coating such as HYDAK (Biocoat, Horsham, Pa.) or another slippery coating as is known in the art. A balance can be struck between the angle of the distal tip, the angle of approach to the dissection entry point and whether or not the tip is covered by a slippery coating such that the risk of penetrating certain tissues (i.e. inner wall of the sclera) is reduced while the ability to penetrate other tissues (i.e. iris root or ciliary body) is maintained.

In addition to tip shape, coatings and pre-curvature of the applier **515**, specific dissection performance also depends in part on the compliance and flexibility of the applier **515**. The compliance and flexibility of the applier **515** is generally a function of the material, material properties and diameter of the material selected for the applier. As mentioned above, it is desirable to have an applier **515** that does not easily penetrate tissues such as the inner wall of the sclera. But it is also desirable to have an applier **515** that can penetrate through other tissues such as the iris root or the ciliary body. Similarly, it is desirable to have an applier **515** that can hug the curve of the inner scleral wall during blunt tissue dissection.

The outer diameter of the applier **515** can be selected and optimized based on the material and flexibility of the material used for the applier **515**. An applier made of nitinol, for example, can have an outer diameter of about 0.009 inches. Nitinol is a superelastic metal that is quite bendable yet is stiff enough to be pushed through the iris root and the ciliary body to reach to and hug the curve of the inner scleral wall during blunt dissection along the boundary between the sclera and the adjacent tissues to the inner scleral wall. When combined with other features of the applier, for example a blunt tip, a nitinol applier having an outer diameter of about 0.009 inches can be used to gently dissect the tissue layers while avoiding tunneling or piercing one or both the inner scleral wall and choroid. Stainless steel spring wire is another material that could be used for the applier **515**. Stainless steel wire is generally slightly stiffer than nitinol. Thus, the outer diameter of an applier made of stainless steel wire may need to be somewhat smaller than the outer diameter for an applier made of nitinol in order to achieve the same performance during blunt dissection. In an embodiment, the applier has an outer diameter of about 0.017 inches. It should be appreciated that for a given material's flexibility, the optimum outer diameter of the applier can be determined and extrapolated for an applier of a different material having a different degree of

flexibility. Other materials considered for the applier **515** include compliant flexible wires made from a polymer or a polymer composite wire reinforced with high-strength fibers.

Methods of Implant Delivery

A method of delivering and implanting the implant into the eye is now described. In general, one or more implants **105** can be slidably mounted on and implanted in or near the suprachoroidal space using a delivery system as described herein. The mounting of the implant on the applier of the delivery system can be aided by a retention layer (or a retention coating on the applier or the internal walls of the implant) that reversibly retains the implant on the tip of the applier while still maintaining a flexible and low profile applier as described above. A retention layer can be used to avoid the implant from falling off the applier inadvertently during delivery until the user actuates the delivery component and effects controlled release of the implant from the applier **515**, for example, upon proximal withdrawal of the applier **515**. The implant **105** is then secured in the eye so that it provides fluid communication between the anterior chamber and the suprachoroidal space.

Implantation can be performed using a viewing lens as shown in FIG. **6**G. A viewing lens **1405** (such as a gonioscopy lens represented schematically in FIG. **6**G) is positioned adjacent the cornea. The viewing lens **1405** enables viewing of internal regions of the eye, such as the scleral spur and scleral junction, from a location in front of the eye. The viewing lens **1405** can optionally include one or more guide channels **1410** that are sized to receive the delivery portion **320** of the delivery system **305**. It should be appreciated that the locations and orientations of the guide channels **1410** in FIG. **6**G are merely for illustration and that the actual locations and orientations can vary depending on the angle and location where the implant **105** is to be delivered. An operator can use the viewing lens **1405** during delivery of the implant into the eye. The viewing lens **1405** can have a shape or cutout that permits the surgeon to use the viewing lens **1405** in a manner that does not cover or impede access to the corneal incision. Further, the viewing lens **1405** can act as a guide through which a delivery system **305** can be placed to predetermine the path of the device as it is inserted through the cornea.

An endoscope can also be used during delivery to aid in visualization. For example, a twenty-one to twenty-five gauge endoscope can be coupled to the implant during delivery such as by mounting the endoscope along the side of the implant or by mounting the endoscope coaxially within the implant. Ultrasonic guidance can be used as well using high resolution bio-microscopy, OCT and the like. Alternatively, a small endoscope can be inserted though another limbal incision in the eye to image the tissue during the procedure.

Each step of implantation can also be visualized using an internal visualization system (see for example U.S. patent application Ser. No. 12/492,085). Visualization can occur continuously during implantation or other procedures without the need for re-positioning or removing one or more components of the imaging systems and without the need for viewing through a goniolens.

With reference to FIG. **7**, the delivery portion **320** is positioned such that the distal tip of the applier **515** and the implant **105** penetrate through a small, corneal incision to access the anterior chamber. In this regard, the single incision can be made in the eye, such as within the limbus of the cornea. In an embodiment, the incision is very close to the limbus, such as either at the level of the limbus or within 2 mm of the limbus in the clear cornea. The applier **515** can be used to make the incision or a separate cutting device can be used. For example, a knife-tipped device or diamond knife can be used to initially enter the cornea. A second device with a spatula tip can then be advanced over the knife tip wherein the plane of the spatula is positioned to coincide with the dissection plane.

The corneal incision can have a size that is sufficient to permit passage of the implant **105** on the applier **515** there through. In an embodiment, the incision is about 1 mm in size. In another embodiment, the incision is no greater than about 2.85 mm in size. In another embodiment, the incision is no greater than about 2.85 mm and is greater than about 1.5 mm. It has been observed that an incision of up to 2.85 mm is a self-sealing incision. For clarity of illustration, the FIG. **7** is not to scale.

After insertion through the incision, the applier **515** can be advanced into the anterior chamber along a pathway that enables the implant **105** to be delivered from the anterior chamber into the suprachoroidal space. With the applier **515** positioned for approach, the applier **515** can be advanced further into the eye such that the blunt distal tip of the applier **515** and/or the implant **105** penetrates the tissue at the angle of the eye, for example, the iris root or a region of the ciliary body or the iris root part of the ciliary body near its tissue border with the scleral spur, to be discussed in more detail below.

The scleral spur is an anatomic landmark on the wall of the angle of the eye. The scleral spur is above the level of the iris but below the level of the trabecular meshwork. In some eyes, the scleral spur can be masked by the lower band of the pigmented trabecular meshwork and be directly behind it. The applier can travel along a pathway that is toward the angle of the eye and the scleral spur such that the applier passes near the scleral spur on the way to the suprachoroidal space, but does not necessarily penetrate the scleral spur during delivery. Rather, the applier **515** can abut the scleral spur and move downward to dissect the tissue boundary between the sclera and the ciliary body, the dissection entry point starting just below the scleral spur near the iris root IR or the iris root portion of the ciliary body. In another embodiment, the delivery pathway of the implant intersects the scleral spur.

The applier **515** can approach the angle of the eye from the same side of the anterior chamber as the deployment location such that the applier **515** does not have to be advanced across the iris. Alternately, the applier **515** can approach the angle of the eye from across the anterior chamber AC such that the applier **515** is advanced across the iris and/or the anterior chamber toward the opposite angle of the eye. The applier **515** can approach the angle of the eye along a variety of pathways. The applier **515** does not necessarily cross over the eye and does not intersect the center axis of the eye. In other words, the corneal incision and the location where the implant is implanted at the angle of the eye can be in the same quadrant when viewed looking toward the eye along the optical axis. Also, the pathway of the implant from the corneal incision to the angle of the eye ought not to pass through the centerline of the eye to avoid interfering with the pupil.

FIG. **8** shows an enlarged view of the anterior region of the eye showing the anterior chamber AC, the cornea C, the iris I, and the sclera S. An implant **105** mounted on an applier **515** can approach the angle of the eye from the anterior chamber AC. As mentioned above, the applier **515** moves along a pathway such that the dissection entry point of the distal tip of the applier **515** can penetrate the iris root IR or the iris root portion of the ciliary body CB near the scleral spur SSp. Other penetration points near the angle of the eye are also considered herein. The surgeon can rotate or reposition the handle of

the delivery device in order to obtain a proper approach trajectory for the applier **515**, as described in further detail below.

The applier **515** with the implant **105** positioned thereupon can be advanced through tissues near the angle of the eye, such as the iris root IR, the ciliary body or the iris root portion of the ciliary body. As the applier **515** is advanced it can penetrate an area of fibrous attachment **805** between the scleral spur and the ciliary body. This area of fibrous attachment **805** can be approximately 1 mm in length. Once the distal tip of the applier **515** is urged past this fibrous attachment region **805**, it then can more easily cause the sclera S to peel away or otherwise separate from the ciliary body and choroid as it follows the inner curve of the sclera A to form the suprachoroidal space SChS. As described above, a combination of the applier's tip shape, material, material properties, diameter, flexibility, compliance, coatings, pre-curvature etc. make it more inclined to follow an implantation pathway that mirrors the curvature of the inner wall of the sclera and between tissue layers such as the sclera S and choroid or the sclera and the ciliary body.

The applier **515** can be continuously advanced into the eye, for example approximately 6 mm. The dissection plane of the applier **515** can follow the curve of the inner scleral wall such that the implant **105** mounted on the applier **515**, for example after penetrating the iris root IR or the iris root portion of the ciliary body CB, can bluntly dissect the boundary between tissue layers of the scleral spur SSp and the ciliary body CB such that a distal region of the implant **105** extends through the supraciliary space SCiS and then, further on, is positioned between the tissue boundaries of the sclera and the choroid forming the suprachoroidal space SChS.

Once properly positioned, the implant **105** can be released. The implant **105** can be released for example by withdrawing the applier **515** such that the implant **105** is effectively pushed in a controlled manner off the tip of the delivery portion **320** with the sheath **510** (for example via the manner described above with reference to FIGS. **6**A-**6**D). A retention layer **512** can optionally be used to assist in retaining the implant **105** on the applier **515** during the steps of delivery. However, the relationship between the retention layer **512** and the implant **105** is readily reversible such that the applier **515** and retention layer **512** can be withdrawn into the sheath **510** to controllably release the implant **105** from the tip of the applier upon arrival at the target location within the eye.

The implant **105** can include one or more structural features that aid to anchor or retain the implant **105** in the target region in the eye. The structural features can include flanges, protrusions, wings, tines, or prongs, and the like that can lodge into the surrounding eye anatomy to retain the implant **105** in place and prevent the implant **105** from moving further into the suprachoroidal space SChS. The structural features also provide regions for areas of fibrous attachment between the implant **105** and the surrounding eye anatomy. FIG. **9** illustrates schematically an approximately 1 mm circumferential band **107** of the implant **105** near the junction of the iris root and the scleral spur SSp along the inside of the scleral wall toward the back of the eye at which fibrous attachment can occur. Fibrous attachment can result, for example, from endothelial cell growth in, around and/or between retention features of the implant **105**. In addition, a small amount of scaring in and around an area of fibrous tissue attachment between the scleral spur and the ciliary body in the region of the iris root portion of the ciliary body can provide for additional fixation to prop up the implant in its target location. A proximal portion of the implant **105** can remain within the anterior chamber AC. In one embodiment, at least 1 mm to 2 mm of the implant (along the length) remains in the anterior chamber.

The implant **105** can be positioned in the eye so that a portion of the implant is sitting on top of the ciliary body CB. The ciliary body CB can act as a platform off of which the implant **105** can cantilever into the suprachoroidal space SChS. The implant **105** can have a relative stiffness such that, when implanted, the implant **105** deforms at least a portion of the tissue adjacent the suprachoroidal space to take on a shape that is different than the natural curvature. In this manner, the implant **105** can lift or "tent" the sclera S outward such that the suprachoroidal space SChS is formed around the distal end of the implant **105**. The tenting of the sclera S as shown in FIG. **9** has been exaggerated for clarity of illustration. It should be appreciated that the actual contour of the tented region of tissue may differ in the actual anatomy. Whether the distal end of the implant **105** is positioned between the sclera and the ciliary body or the sclera and the choroid, the implant **105** can act as a flow pathway between the anterior chamber AC and the suprachoroidal space SChS without blockage of the outflow pathway by surrounding tissues such as the sclera or the choroid.

The implant can also be positioned in the eye such that a portion of the implant exerts a force or pressure on or against the ciliary body. The implant can exert a displacing force against the ciliary body such that the implant interferes with and/or resists the natural curvature of the ciliary body. The implant can interfere with and locally change the curvature of the boundary between the sclera and at least a portion of the ciliary body when implanted in the eye. As mentioned previously, the ciliary body produces aqueous humor. The force exerted by the implant on the ciliary body can decrease production of aqueous humor from ciliary body. The stiff configuration of the implant **105** can push down or radially inward on the ciliary body

In an embodiment, an implant **505** can be an elongate, stiff shunt having an internal lumen and an expanded and/or expandable region **510** (see, FIG. **10**A-**10**D). The implant **505** can shunt aqueous from the anterior chamber to the suprachoroidal space. The expandable region **510** of the implant **505** can impart a pressure against the ciliary body CB such that aqueous production is reduced. The pressure can be in a downward direction or a radially inward direction on the ciliary body CB. In an embodiment, the pressure against the ciliary body CB causes at least a portion of the ciliary body CB to be displaced and aqueous production reduced. In another embodiment, the implant does not displace the ciliary body CB but simply exerts pressure against the ciliary body to reduce aqueous humor production. The combination of reduced aqueous production and the shunting of aqueous out of the anterior chamber can act in coordination to reduce pressure within the anterior chamber.

The implant **505** can be an elongated tubular member having a proximal end, a distal end, and a structure that permits flow of fluid (such as aqueous humor) along the length of the implant such as through or around the implant from the anterior chamber. For example, the implant **505** can have at least one internal lumen having at least one opening for ingress of fluid and at least one opening for egress of fluid. The implant **505** need not include an internal lumen that fluidically communicates with the anterior chamber AC. The implant **505** can be a solid bar that allows for flow of aqueous humor along an outside surface. The implant **505** can also permit no flow of aqueous humor through or around the implant and instead apply only a force on the ciliary body to reduce aqueous humor production.

The implant **505** can have a variety of shapes and configurations. The implant **505** can have a shape or take on a shape that optimizes the radial pressure exerted on the ciliary body CB. The implant **505** can be or include an inflatable balloon, expandable spacer or cage, or other configuration. The implant **505** can have one or more expandable regions of Hydrogel **510**. The implant **505** can also have a variety of cross-sections and shapes. For example, the implant can have a circular, oval, rectangular or star shape and can vary in cross-sectional shape moving along its length. In an embodiment, the implant **505** can have a star or cross-shape such that aqueous from the anterior chamber flows through one or more convoluted outer surface of the implant.

The pressure exerted by the implant **505** on the ciliary body CB can vary. In an embodiment, the implant **505** exerts a radially-inward (relative to the center of the eye) force on the ciliary body CB. In another embodiment, the implant exerts a force that has a component that points radially inward and another component that does not point radially-inward.

While this specification contains many specifics, these should not be construed as limitations on the scope of an invention that is claimed or of what may be claimed, but rather as descriptions of features specific to particular embodiments. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or a variation of a sub-combination. Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Only a few examples and implementations are disclosed. Variations, modifications and enhancements to the described examples and implementations and other implementations may be made based on what is disclosed.

What is claimed is:

1. An ocular implant, comprising:

an elongate member having a proximal portion and a distal portion, at least one inlet port located at the proximal portion of the elongate member, and at least one outlet port in fluid communication with the inlet port, wherein the elongate member is adapted to be positioned in the eye such that the at least one inlet port communicates with the anterior chamber, the at least one outlet port communicates with the supraciliary space, and wherein the elongate member provides for aqueous fluid to flow from the anterior chamber toward the suprachoroidal space when the elongate member is implanted in the eye; and

wherein the elongate member comprises a wall material imparting a sufficient stiffness to the elongate member such that after implantation the elongate member is able transition from a curved shape to a less curved shape to deform at least sub-scleral eye tissue so as to form a tented volume beneath the sclera.

2. The implant of claim **1**, wherein the stiffness of the elongate member is greater than a stiffness of at least a portion of the eye tissue surrounding the supraciliary space.

3. The implant of claim **1**, wherein the elongate member forms a straight chord relative to a curvature of the supraciliary space.

4. The implant of claim **1**, wherein the eye tissue surrounding the supraciliary space comprises an outer tissue shell having a first boundary and a first curvature and an inner tissue shell having a second boundary and a second curvature, wherein the first curvature and the second curvature form a ratio wherein the stiffness of the elongate member changes the ratio between the first curvature and the second curvature.

5. The implant of claim **4**, wherein the elongate member is curved such that it intersects, but does not conform to the first or second curvatures when implanted.

6. The implant of claim **1**, wherein the wall material has a Young's modulus that is less than 30,000 pounds per square inch.

7. The implant of claim **1**, wherein the wall material has a Young's modulus that is between about 30,000 pounds per square inch and 70,000 pounds per square inch.

8. The implant of claim **1**, wherein the wall material has a Young's modulus that is approximately 200,000 pounds per square inch.

9. The implant of claim **1**, wherein the wall material has a Young's modulus that is less than or equal to 40,000,000 pounds per square inch.

10. The implant of claim **1**, wherein the elongate member further comprises an internal lumen.

11. The implant of claim **1**, wherein the elongate member is configured such that a distal end of the elongate member presses against the sclera and a portion of the elongate member presses against and deforms the ciliary body to form the tented volume.

12. An ocular implant system for implantation into an eye, comprising:

an elongate member comprising:

a wall material imparting a sufficient stiffness to the elongate member such that, after positioning the elongate member in a deployed location in the eye, the elongate member is able to transition from a curved shape to a less curved shape to deform sub-scleral eye tissue adjacent the elongate member so as to form a tented volume beneath the sclera;

at least one inlet port located at a proximal portion of the elongate member; and

at least one outlet port in fluid communication with the inlet port;

wherein when the elongate member is positioned in the deployed location, the at least one inlet port communicates with the anterior chamber and accepts inflow of aqueous humor and further wherein the at least one outlet port is positioned to drain aqueous humor toward the suprachoroidal space.

13. The implant system of claim **12**, wherein the elongate member is configured to form a straight chord relative to a curvature of the sclera when the elongate member is positioned in the deployed location.

14. The implant system of claim **13**, further comprising:

a delivery instrument comprising an elongated applier element formed of an elongated body that removably couples to the elongate member,

wherein the delivery instrument is configured to introduce the elongate member into the anterior chamber through a corneal incision, advance the elongate member through the anterior chamber, detach at least a portion of the ciliary body from the sclera to form an internal space between the ciliary body and the sclera, advance the elongate member through the internal space, and detach

the elongate member from the elongated applier element and into the deployed location.

15. The implant system of claim **14**, wherein the applier element is curved, and wherein the elongate member is sufficiently flexible so as to conform to a curvature of the applier element when removably coupled to the applier element, and wherein, upon detachment of the elongate member from the applier element, the elongate member transitions to a shape that forms a substantially straight chord relative to a curvature of the sclera to form the tented volume.

16. The implant system of claim **15**, wherein the elongate member comprises an internal lumen and wherein the applier element extends through the internal lumen when the elongate member is removably coupled to the applier element.

17. The implant system of claim **16**, the delivery instrument further comprises a sheath positioned axially over a proximal portion of the applier element, wherein a distal end of the sheath abuts a proximal end of the elongate member when the elongate member is removably coupled to the applier element, and wherein the sheath acts as a stopper that impedes the elongate member from moving in a proximal direction relative to the delivery instrument as the applier element is detached from the elongate member.

18. The implant system of claim **14**, wherein the elongate member comprises an internal lumen and wherein the delivery instrument comprises:

a handle component;

a stopper element comprising a distal portion of a sheath fixedly positioned relative to the handle component, wherein the sheath is positioned proximally of the elongate member when the applier element is removably coupled to the elongate member;

wherein the applier element is movably positioned relative to the sheath and extends longitudinally through the sheath, the elongated applier element sized to be longitudinally inserted through the internal lumen of the elongate member for removably coupling the delivery device to the elongate member, wherein the sheath is positioned proximally of the elongate member when the applier element is removably coupled to the elongate member.

19. The implant system of claim **13**, wherein the stiffness of the elongate member is greater than a stiffness of eye tissue adjacent the elongate member when the elongate member is positioned in the deployed location and wherein at least a portion of the tented volume is within the supraciliary space.

20. The implant system of claim **13**, wherein the elongate member is configured to form a chord relative to a curvature of the sclera when the implant is positioned in the deployed location.

21. The implant system of claim **13**, wherein the eye tissue surrounding the tented volume comprises an outer tissue shell having a first boundary and a first curvature and an inner tissue shell having a second boundary and a second curvature, wherein the first curvature and the second curvature form a ratio, wherein the stiffness of the elongate member is configured to modify the ratio between the first curvature and the second curvature when the elongate member is positioned in the deployed location.

22. The implant system of claim **21**, wherein the elongate member is shaped such that it intersects, but does not conform to the first or second curvatures when implanted in the deployed location in the eye.

23. The implant system of claim **13**, wherein when the elongate member is positioned in the deployed location, the outlet port is positioned in at least one of the supraciliary space and suprachoroidal space.

24. The implant system of claim **13**, wherein when the elongate member is positioned in the deployed location, the outlet port is positioned in the supraciliary space.

25. The implant system of claim **13**, wherein when the elongate member is positioned in the deployed location, the outlet port is positioned between the sclera and the ciliary body.

26. The implant system of claim **13**, wherein the elongate member includes multiple outlet ports positioned along a distal region of the elongate member and wherein when the elongate member is positioned in the deployed location, the outlet ports are positioned between the ciliary body and the sclera.

27. The implant system of claim **13**, wherein the elongate member comprises an internal lumen.

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